1   UNITED STATES DISTRICT COURT
                   FOR THE DISTRICT OF NEW JERSEY
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UNITED STATES OF AMERICA, et   CIVIL ACTION NUMBER:
4   al,
          Plaintiffs,   3:12-cv-07758-ZNQ-JBD
5
          v.   JURY TRIAL - VOLUME 19
6

JOHNSON & JOHNSON, JANSSEN
7   PRODUCTS, L.P.
          Defendants.
8   _____
          Clarkson S. Fisher Building & U.S. Courthouse
9   402 East State Street
          Trenton, New Jersey 08608
10   June 7, 2024
          Commencing at 12:00 p.m.
11

B E F O R E: THE HONORABLE ZAHID N. QURAISHI,
12   UNITED STATES DISTRICT JUDGE

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 1            (PROCEEDINGS held in open court before The Honorable

 2   ZAHID N. QURAISHI, United States District Judge, on June 7,

 3   2024, at 12:00 p.m.)

 4            THE DEPUTY COURT CLERK:  All rise.

 5            THE COURT:  Thanks, folks.  Everyone may be seated,

 6   or you can stand if you're going to give appearances, but

 7   let's have appearances from counsel, beginning with Relators,

 8   and then we'll hear from Janssen.

 9            MR. MARKETOS:  Good morning, Your Honor.

10   Pete Marketos for the Relators.

11            MS. WENDEL:  Good morning.  Whitney Wendel for

12   Relators.

13            MR. WIRMANI:  Good morning.  Andrew Wirmani for

14   Relators.

15            MR. RUSS:  Good morning.  Josh Russ for Relators.

16            THE COURT:  All right.  Good morning, folks.

17            MS. BROWN:  Good morning, Your Honor.  Alli Brown for

18   Janssen.

19            MR. WYATT:  Good morning.  Geoff Wyatt for Janssen.

20            MR. KLEIN:  Good morning.  Brad Klein for Janssen.

21            THE COURT:  All right.  Good morning, folks, as well.

22        I don't know if we have any other issues, but let me

23   talk about the ones that I have.  So the first is I want to go

24   in reverse order before we get into the adverse inference

25   instruction and whether that's going to be in the final
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1 instructions or just read to the jury today. Can we talk

2 about the email from Mr. Wyatt?

3   So, Mr. Wyatt, I got your email about the -- bringing

4 an FCA claim instruction.

5   Mr. Marketos, have you had an opportunity to review

6 that?

7   MR. MARKETOS: I have not, Your Honor. I'm sorry.

8 Excuse me. Which email was that?

9   THE COURT: It's an email --

10   MR. MARKETOS: Did it just come in --

11   THE COURT: It's 10:08 a.m. today. I don't know if

12 you put eyes on it yet. It's not a very lengthy instruction.

13 It's just a proposal to include -- there was another

14 instruction that I gave during the trial that Janssen is

15 asking for me to include in the final instructions. It's -- I

16 want to talk about that first because I think that's an easier

17 one.

18   MR. MARKETOS: I'm sorry. Would Your Honor mind if I

19 take the time to look at it and respond to it --

20   THE COURT: How about I just tell you what it is.

21   MR. MARKETOS: Sure.

22   THE COURT: So I gave an instruction during the

23 trial, and I believe it was connected to Donna Graham's

24 testimony. I ended up -- because we had heard about the

25 Department of Justice. Mr. Marketos, do you remember this?

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1 They kept bringing up the DOJ, and I said, In order for a

2 private citizen to bring claims under the False Claims Act,

3 the private citizen must disclose his or her allegations to

4 the Department of Justice. The private citizen, known as the

5 Relator, may then pursue his or her claims in federal court.

6 The Department of Justice is not involved in this case for

7 purposes of this trial.

8   This was an instruction that we had discussed in great

9 length and back and forth from both sides. And that was an

10 instruction that I gave in the trial. I think Janssen's just

11 making sure or asking or requesting that this be included in

12 the final instructions. I just want to get a sense of whether

13 you would oppose this or not.

14   MR. MARKETOS: Yes, Your Honor.

15   THE COURT: Why?

16   MR. MARKETOS: Because it was specific to Ms. Graham

17 and she filed a separate claim. And that was why you gave the

18 instruction, because -- Ms. Donna -- that's why I had Ms.

19 Donna Graham in there. What we were saying with respect to it

20 not being -- the government not being involved in this case,

21 we had a problem with that as well because the government --

22   THE COURT: But that's the instruction I gave, so it

23 doesn't matter that you objected to that language back then.

24 I disagreed and gave that instruction.

25   MR. MARKETOS: Oh, no. I'm sorry. I'm talking about

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 1   their wanting to revise it now to eliminate Ms. Donna Graham

 2   from the instruction.

 3   THE COURT: But you want me to give -- let's talk

 4   about this for a second. I don't even think I should -- just

 5   to be clear, this idea of using an instruction as you have

 6   heard testimony in this case, I would never put that into a

 7   final instruction for the jury. What I'm proposing -- it's a

 8   modification of what Mr. Wyatt submitted, so I want to be very

 9   clear -- is this instruction will be entitled "Bringing an FDA

10   Claim," which is a fairly benign title, but you guys can tell

11   me if you object to that. And it would not lead off You have

12   heard testimony in this case; otherwise, I'll be giving 1,000

13   instructions to this jury in the final instructions, because

14   they've heard a lot of testimony.

15   What I am proposing to do and I'm inclined to do is

16   say, In order for a private citizen to bring claims under the

17   False Claims Act, the private citizen must disclose his or her

18   allegations to the Department of Justice. The private

19   citizen, known as the Relator, may then pursue his or her

20   claims in federal court. The Department of Justice is not

21   involved in this case for purposes of this trial.

22   That's an instruction that I already gave to them to

23   explain why the plaintiffs were called Relators in this case,

24   because I find that to be confusing to laymen jurors who don't

25   know how a qui tam case is brought or what the terminology is.

1 And because they kept hearing about the Department of Justice,

2 we gave that instruction.

3   Why would we not allow that instruction to be in the

4 final instructions if I instructed them on that part of

5 bringing an FCA claim at the time of trial?

6   MR. MARKETOS: Your Honor, for -- only for two

7 reasons, and this only has to do with the word "involve."

8 That's all I'm addressing right now, and everything else is

9 fine. They are involved, and --

10   THE COURT: Not for purposes of this trial, which is

11 why we added that language.

12   MR. MARKETOS: Right. So for the -- meaning they're

13 not present, but they are involved. They can intervene; they

14 can dismiss; they can move to dismiss; and they filed a

15 statement of interest. Okay. So I understand what you're

16 saying here. You get my issue here.

17   THE COURT: I understand your issue. But I think

18 that doesn't complicate anything because the jury is not aware

19 of the concerns that you're raising about all those issues.

20 All we are telling them is that the Department of Justice is

21 not in this courtroom involved in this particular trial. I'm

22 not -- and that was the instruction I already gave them. So

23 if we're going to back, say, Judge, we disagreed with that

24 instruction you gave at the time of trial, then your objection

25 is noted, but I'm not changing the instruction at the end of

1 the trial. Right? I mean, it's required to be consistent.

2 The only change I would make is I'm not going to add these --

3 the preface of You've heard testimony in this case. I don't

4 think that's appropriate. I think I can tell them, In order

5 for a private citizen to bring a claim under the FCA, and then

6 the rest of those sentences.

7   So my understanding is you object to the language, but

8 I'm telling you I'm going to put it in.

9   MR. MARKETOS: I understand, Your Honor. When it was

10 brought in the context of Ms. Graham, it made more sense.

11   THE COURT: Well, it wasn't brought just in the

12 context of Ms. Graham. What happened is Ms. Graham was

13 testifying, and so I decided at that time it was appropriate

14 to give that instruction because they had just been hearing

15 about the Department of Justice and Relators, and it

16 probably could have been given at the outset of the case. But

17 neither party proposed any instructions to educate this jury

18 about qui tam or what a Relator is or how a False Claims Act

19 case is brought. And so while the trial is going on, they

20 keep hearing about the Department of Justice and Relators, and

21 I think that's confusing to the jurors. So at that point, I

22 said, We're going to give some kind of instruction so we can

23 move on from this.

24   So I understand that it was somewhat tangentially

25 connected to Ms. Graham's testimony, but that instruction

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1 could have been given at any time in this trial, including

2 prior to the trial beginning and in the preliminary

3 instructions.

4   MR. MARKETOS: I understand, Your Honor. There is an

5 instruction that was given -- and it was read to the jury at

6 the outset of the case, and it will be in the final

7 instructions -- that talks about a Relator bringing claims on

8 behalf of the government. So it's a little bit confusing to

9 have both --

10   THE COURT: Which instruction is that?

11   MR. MARKETOS: It's in the preliminary instructions

12 and the proposed final. It talks about Relators bringing a

13 case on behalf of the federal government. Let me pull it up

14 for Your Honor.

15   And so they're going to have two instructions. They

16 are bringing it on behalf of the federal government but the

17 government is not involved. Right? That's the issue that

18 I've got. I was wondering if we might just be able to take a

19 look at it and propose a slight tweak to it to make it more

20 accurate. I don't want there to be two conflating

21 instructions.

22   THE COURT: You have until lunch.

23   MR. MARKETOS: Okay, Your Honor. And I appreciate

24 what Your Honor's saying --

25   THE COURT: I'm inclined to give it. I'm inclined to

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 1   give it verbatim as I gave it to the jury during the trial.

 2   But you have until lunch if there is some proposed revision,

 3   but I'm telling you that I'm not inclined to do it, but I

 4   won't prohibit you from at least proposing it, but you guys

 5   have until the end of the lunch break.

 6           MR. MARKETOS:  Yes, Your Honor.  Thank you.

 7           THE COURT:  We don't have a lunch break.

 8           MR. MARKETOS:  Oh, yeah.  How about...

 9           THE COURT:  We'll take a 15-minute break at some

10   point this morning, so somebody on your team should be working

11   on that issue as we are going through witnesses.

12           MR. MARKETOS:  We'll do it.  Thank you.

13           THE COURT:  All right.

14        I thought that was going to be the easy one.  So that

15   didn't work out.  So why don't we talk about the adverse

16   inference instruction.

17        By the way, Mr. Marketos, it sounds like with the

18   adverse inference instruction, you're more than happy to have

19   that in the final instructions because the jury is going to be

20   instructed about it today during the trial.

21           MR. MARKETOS:  I'm more than happy to have this

22   instruction as well, Your Honor --

23           THE COURT:  Do you see what my -- here is my concern,

24   though.  Right?  We need to be consistent.  I'm going to say

25   this at the outset because Janssen's going to have an
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 1   opportunity to speak.  Final instructions are really supposed

 2   to be a summary of the instructions that were provided to the

 3   jury, preliminary instructions, instructions given during the

 4   trial, so they have it, which, by the way, supports giving the

 5   adverse inference instruction in the final instructions and in

 6   written form with all the other instructions, not carved out

 7   where they are given a ten-second instruction and then, five

 8   days later, they don't hear about it again and then the

 9   parties might close on it and now we are stuck with these

10   jurors hoping they memorized verbatim what I said today for

11   about 10 or 15 seconds, which is a very dangerous thing to do,

12   which is why we summarize all these instructions.  So what I'm

13   telling you is, if you're going to argue that the adverse

14   instruction that I give today should be included in the final

15   instruction, are you telling me that Janssen should have the

16   ability to revise that instruction for purposes of the final?

17   Because that's what you're asking to do with the

18   bring-an-FCA-claim instruction.

19        I gave that specific instruction to the jury.  And

20   you're asking for an opportunity to revise that instruction

21   different than what I told them during the trial in the final

22   instruction.  Should Janssen be able to say, Look, Your Honor,

23   we know your ruling.  You've decided to give this adverse

24   instruction today during the trial, but we would like to

25   propose revisions before it makes it into the final.  Do you
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 1   see how that's not something that I'm likely to do?

 2              MR. MARKETOS:  I have 15 minutes to figure it out,

 3   Judge.

 4              THE COURT:  All right.

 5              MR. MARKETOS:  No, I understand what you're saying.

 6   I do.  I did point this out when -- I did point this issue out

 7   then, and I just -- I did point it out then.  It was a Donna

 8   Graham issue.  I did point it out, and there was language in

 9   the original instruction with respect to a Relator bringing a

10   case on behalf of the federal government.  I just want to

11   highlight that issue for the Court.  I do believe this should

12   go in the final instruction.

13              THE COURT:  All right.  That's fair.  Again, when we

14   have that 15-minute break or so, that's what I'm hoping you

15   guys will have some opportunity to address.

16              MR. MARKETOS:  Yes, Your Honor.

17              THE COURT:  With the adverse instruction, then, I

18   presume your position is it should be in the final instruction

19   because I'm instructing them during the trial.

20              MR. MARKETOS:  Yes, Your Honor.

21              THE COURT:  Mr. Wyatt, let me hear from you, but I

22   will tell you -- let me just hear from you.  I understand that

23   you oppose that, but walk me through it, and I did read your

24   email, but you might as well put it on the record.

25              MR. WYATT:  Sure.  I appreciate that, Your Honor.
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 1   Let me just start with agreeing with the general proposition

 2   the Court put out there, which is that, in general, an

 3   instruction is given during the course of the trial, makes

 4   sense to give it in the final instruction. So I have my work

 5   cut out for me, and I recognize that. My concern is that this

 6   is more than just a jury instruction. It's also a sanction,

 7   and it does have -- the cases recognize a potentially stinging

 8   and perhaps even decisive impact on the way the jurors will

 9   look at the evidence. I realize, of course, in part, that's

10   the point, and I'm not trying to fight that, and I'm certainly

11   not trying to belabor any of the issues that we've discussed a

12   number of types now. I'm merely talking about what is the

13   likely impact on the jury, and we cited some case law to Your

14   Honor.

15   THE COURT: Let me ask you this, Mr. Wyatt. And, by

16   the way -- and I don't think your point is unreasonable.

17   Right? I will be candid. This is a unique instruction in

18   many ways. It is not a typical jury instruction. It is not

19   one that is commonly given in trial. I think I voiced this

20   before, but I think it's tragic that I made a finding that I

21   have to give this instruction. It's not something I want to

22   do, and like I said before, I think the lawyers in this case,

23   trying this case, as much as you have had disputes in the last

24   five weeks, have all been professional and excellent in your

25   performance in the case. That part I won't take away from

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 1  either side.  That being said, it's unique, but here's some of

 2  my concerns, and maybe you'll address them.  The first is we

 3  isolate this instruction different from every other

 4  instruction I've given to the jury, I'm uncomfortable there.

 5       But here's another concern I have.  And maybe you're

 6  not concerned, but there could be prejudice to Janssen here.

 7  That instruction says they may but are not required to infer.

 8  Five days from now, when they've never heard about this

 9  instruction again, I have concerns they can be in

10  deliberations thinking, Judge Quraishi told us we have to hit

11  Janssen here, that they messed up and we need to take this out

12  on them; we have to infer.

13       How do I know that that's not going to be the

14  recollection of these eight jurors a week from now when

15  they're in there, as opposed to they have the language; that

16  I've given them the opportunity to infer that but they're

17  absolutely not required to and I'm not telling them they

18  should?

19       So in one part, I am concerned about additional

20  prejudice to the defense when the instruction gives them the

21  ability to make that inference but the Court is not directing

22  them to, which is a very different instruction, right, and one

23  that I would never give, that they are required to make a

24  negative inference here.

25       Do you have any concerns about that, or -- because
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 1  that's one of them.  The reason why we have all these

 2  instructions incorporated in the final is we cannot expect any

 3  jury to memorize the instructions that we give in real time or

 4  even the ones I gave at the outset of the trial, which is why

 5  all those preliminary instructions that I spent time reading

 6  get read to them again in the final instructions.  They can't

 7  even be expected to memorize the role of the jury before the

 8  final instruction.

 9       This one I agree with you is a serious one.  But don't

10  you have concerns about their recollection being inaccurate?

11       MR. WYATT:  Well, first of all, Your Honor, let me

12  just say I appreciate the Court's comments about the lawyering

13  in the case.  I really do appreciate that.

14       With respect to the comment about what the jury may

15  remember, I agree that's a valid concern, what the jury's

16  going to remember about the instruction.  My concern is that

17  it's more problematic to repeat the instruction because it

18  really does -- I fear that this instruction is going to be

19  received by the jury as an instruction of really how they

20  should conclude the evidence -- what the evidence means.

21       And so my concern about that outweighs my concern about

22  the other issue Your Honor raised, which is perhaps they'll

23  misremember the instruction.  I don't think they will, because

24  I candidly believe -- and Relators will do what they do -- but

25  I suspect that they will put the language up on the screen or
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 1   recite it to the jury in closing and so it will be fresh in

 2   their minds. And it will also have only been said a few days

 3   before closing anyway.

 4   So I don't think they'll forget it. So my bigger

 5   concern is simply the punitive impact that the instruction may

 6   have, I think.

 7   THE COURT: They may need to refer to that

 8   instruction, though. Like any other instruction that's given

 9   to the jury in deliberation, we don't know how long they'll be

10   deliberating, and we don't know at what point during their

11   deliberations a juror or a group of jurors will need to refer

12   back to the instructions.

13   I'm not saying they will ever refer to this instruction

14   at all. I don't -- I can read the tea leaves just like all of

15   you. But to not have that instruction before them -- one

16   other thing I'll say: I know there's no case law to support

17   not putting it in the final. I know the practice is -- at

18   least some of my colleagues in this district, at least, and

19   this is not binding on me in any sort of way -- but the

20   practice is if a negative or an adverse inference is given,

21   that it is included in the final instructions.

22   That's not binding on me, which is why I wanted to hear

23   argument and see what the parties' positions were in the case.

24   But my concerns with isolating this instruction, I

25   think, outweigh, I think, the concern that you've raised,

 1 Mr. Wyatt. Giving an instruction, any instruction, including

 2 one, I think, as important as this one -- maybe can't be one

 3 that I give within mere seconds in a trial day without any

 4 reminder to them or any reference to that instruction.

 5   I'm concerned about the memory of the jurors. I'm

 6 concerned that they've been give multiple instructions, all of

 7 which will be repeated in the final instruction except for

 8 this one. And also, the purpose of the final instructions is

 9 to summarize all the instructions given to the jury, including

10 ones that come up in real time during the trial, so that they

11 have access to those instructions during deliberations if and

12 when they may need to refer to them.

13   So the objection of Janssen is fully noted, but I'm

14 going to include the adverse inference instruction in the

15 final instructions. So you should be prepared to see that

16 when you get the draft of the final instructions today.

17   I will tell you, Mr. Marketos, for now I'm including

18 the bring-an-FCA-claim instruction into that proposed or draft

19 final instruction that I'm going to be sending to the parties

20 today with one caveat: that I will hear from you if you

21 believe that it would cause some confusion by a prior

22 instruction that's also going to be given, and we'll deal with

23 that on the break. Fair enough?

24   MR. MARKETOS: Yes, Your Honor. Thank you.

25   THE COURT: All right. Those two issues have been

1   addressed.

2   What else do we have to talk about this afternoon?

3   Mr. Marketos, do we have something more?

4   MR. MARKETOS: No, Your Honor. We're ready to go.

5   THE COURT: Ms. Brown -- Mr. Wyatt?

6   MR. WYATT: We're ready to go as well, Your Honor.

7   THE COURT: All right. Then why don't we do this,

8   folks, if we have nothing else. Why don't you guys take a

9   break. We are at about a 15-minutes recess for when the

10 jurors are ready, and then I'll bring them out and we'll

11 continue with the examination.

12   Thanks, folks. You can all remain seated.

13   (A short recess occurred.)

14   THE DEPUTY COURT CLERK: Please remain seated.

15   THE COURT: By the way, when is Ms. Kaucher

16 testifying? After this witness?

17   MS. BROWN: Yes, Your Honor.

18   THE COURT: All right. Do me a favor. Counsel, do

19 you mind just approaching? I just want to you look at -- Kim,

20 can you give this to Mr. Marketos and Ms. Brown.

21   Only because -- look, it's a sensitive instruction. I

22 want to make sure that this is the instruction that we've been

23 debating for three days. There's been so many back-and-forths

24 that I want to be clear that I'm not reading the wrong draft

25 or a different proposal.

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 1        But that is the one that I understood we were there

 2   with at the end of the day, but I do want to make sure that

 3   with all the different drafts that have come my way.

 4        MR. MARKETOS:  Your Honor, one point very quickly,

 5   separate from this, if I may?

 6        THE COURT:  Yes.

 7        MR. MARKETOS:  The --

 8        THE COURT:  Folks, everybody can be seated -- I'm

 9   sorry -- except for Mr. Marketos, who is speaking.

10        MR. MARKETOS:  Thank you.

11        The original instruction refers to Relators bringing

12   claims on behalf of state government.  Proposed agreed

13   Instruction Number 2 and the proposed final instruction refers

14   to Relators bringing claims on behalf of the federal

15   government for the False Claims Act and with respect to state

16   law claims as well.  Twice in the agreed instructions for

17   proposed final.  I just wanted to make sure I said it right.

18        THE COURT:  Okay.

19        MR. MARKETOS:  Okay.

20        THE COURT:  But that doesn't change -- you're still

21   going to -- by the way, just because we're on this note, I

22   looked at Instruction Number 2 --

23        MR. MARKETOS:  Yes.

24        THE COURT:   -- where it says Relators in quotes.

25   What I'm thinking makes sense is not to have me bring an FCA
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 1  claim instruction separate, but that little paragraph that I

 2  instructed the jury on would go right after that.

 3          MR. MARKETOS:  Yes, Your Honor.

 4          THE COURT:  So it would go paragraph where you

 5  identify Relators, the instruction I gave to the jury about

 6  Relators bringing claims and -- to the Department of Justice,

 7  and then it goes into the statement of the case.  So I think

 8  that's where I would propose to stick it as opposed to

 9  separate to avoid any possible confusion.  But when I looked

10  at it, it was not inconsistent.  It was just elaborating.

11      So when you look at it for the break, that's where I

12  intend to insert it, after the first paragraph of

13  Instruction 2 where you first bring up the term Relators in

14  quotes.

15          MR. MARKETOS:  Very good.

16          THE COURT:  All right?

17          MR. MARKETOS:  Thank you.

18          THE COURT:  Now, Mr. Marketos, is this the

19  instruction for the adverse inference?  I want to make sure.

20          MR. MARKETOS:  It is, Your Honor.

21          THE COURT:  Mr. Wyatt?

22          MR. WYATT:  Yeah, it is one, but one thing I didn't

23  catch earlier, though, that I'll just raise, I think the

24  allegations referred only to Prezista and not Intelence, based

25  on the documents.  So that would be a change I would suggest
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 1 making for accuracy.

 2   But with respect to what's in the instruction, this is

 3 what we've been discussing as far as I recall.

 4   THE COURT: All right. I mean, I don't have the --

 5 look, I know I have the documents, but I'm not looking at them

 6 currently on the bench. Do you have the documents,

 7 Mr. Marketos, and what is your understanding?

 8   MR. MARKETOS: She raises allegations with respect to

 9 both drugs, Your Honor.

10   THE COURT: Prezista and Intelence.

11   MR. WIRMANI: Yes, Your Honor, if I may, since it's

12 my witness.

13   She makes -- in the letter that she wrote to Janssen,

14 she raised, I think, six allegations. One of them was that

15 the comp system that Janssen had was encouraging the off-label

16 marketing of Intelence in naive patients. So her allegations

17 encompass both Prezista and Intelence.

18   THE COURT: All right.

19   Mr. Wyatt?

20   MR. WYATT: I'll accept that representation, Your

21 Honor. I'm looking at a different document. They may not all

22 say the same thing. So I'm not going to --

23   THE COURT: Yeah. Look, I don't think you're wrong.

24 I think there may be some documents that refer to

25 Ms. Cesario's allegation that touch on both drugs. There may

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 1   be other documents that talk about off-label promotion of

 2   Prezista only, but I don't think this is inaccurate.

 3        And also, because if some documents relate to both, I

 4   think that's sufficient for purposes of the instruction, but I

 5   hear you.

 6        So double-check that, but unless you tell me that

 7   there's no document that involves Intelence in these

 8   allegations -- and I think that's probably the least material

 9   piece of this instruction that the jury is going to get.

10             MR. WYATT:  I don't disagree with that, Your Honor.

11             THE COURT:  All right, all right.  That's fair.

12        But other than that, the language is the ones that we

13   have discussed, the final draft, as opposed to these prior

14   markups, including ones that I've made.  So this is for me to

15   just double-check myself because it's an important instruction

16   that I want to make sure is verbatim with what we all

17   discussed in the final version.

18             MR. MARKETOS:  It is, Your Honor.

19             MR. WYATT:  I believe it is as well, Your Honor.

20             THE COURT:  All right.  That's all.

21        Should we get Dr. Rosenberg back on witness stand?

22             MS. BROWN:  Yes, Your Honor.

23        (The jury enters the courtroom.)

24             THE COURT:  All right, folks.  Everybody can have a

25   seat.
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United States District Court
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1   Members of the jury, welcome back. Happy Friday. And

2   we're going to continue with examination of witnesses like we

3   have been. So that's nothing new.

4   And with that, Doctor, I just want to remind you you're

5   still under oath from yesterday.

6   And Mr. Wirmani, when you're ready to proceed with

7   cross-examination, you may.

8   MR. WIRMANI: Thank you, Your Honor.

9   (**SCOTT ROSENBERG, M.D.**, HAVING BEEN PREVIOUSLY SWORN/AFFIRMED,

10   TESTIFIED AS FOLLOWS:)

11   (CROSS-EXAMINATION BY MR. WIRMANI:)

12   Q.   Dr. Rosenberg, welcome back.

13   When we stopped yesterday, we were talking about the

14   factors that you personally consider in making prescribing

15   decisions.

16   Correct?

17   A.   Correct.

18   Q.   And you talked about the different factors that go into

19   your medical analysis.

20   Fair?

21   A.   That's fair.

22   Q.   You confirmed for the jury that you're not speculating or

23   offering opinions about how other doctors make prescribing

24   decisions.

25   Correct?

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District of New Jersey

1 A.   Sort of. I -- I think that, you know, what I do is also

2 what I and my colleagues teach hundreds of trainees to do that

3 are spread throughout the country.

4 Q.   Dr. Rosenberg, yesterday you said you weren't offering

5 opinions or speculating about what other doctors do. You were

6 talking --

7 A.   I'm not --

8   THE COURT: I'm sorry, Doctor, you just got to wait

9 for the full questions and then you can --

10   THE WITNESS: I'm sorry.

11 BY MR. WIRMANI:

12 Q.   You were talking about your personal prescribing

13 decisions.

14   Correct?

15 A.   Yes.

16 Q.   Okay.

17   And you confirmed for us that you are not offering an

18 opinion -- you weren't asked to offer an opinion about the

19 standard of care or what is medically and reasonably necessary

20 with respect to HIV patients that have preexisting lipid

21 issues.

22   Correct?

23 A.   Correct.

24 Q.   And you also confirmed for us that you are not here to

25 testify about opinions, that you have not been asked to offer

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1   opinions about Prezista's marketing messages.

2   Correct?

3   A.   Correct.

4   Q.   And specifically, you're not offering opinions -- you

5   weren't asked to offer opinions about Prezista's marketing

6   messages with respect to its lipid profile or its impact on

7   lipids.

8   Correct?

9   A.   Correct.

10 Q.   And you gave the jury some hypotheticals that you said

11 were outliers, not the fact of this case.

12   Fair?

13 A.   I presented hypotheticals to try to represent how nuanced

14 individuals with HIV infection can be, and some of those cases

15 were, you know -- and they were all unusual because the point

16 I was trying to make is that all patients are different and

17 that there's no one size fits all. And so that was really the

18 point in presenting somewhat unusual cases.

19 Q.   Correct.

20   You were pointing the jury to unusual fact patterns and

21 how you apply your medical knowledge to those fact patterns.

22   Fair?

23 A.   That's fair, but can I explain further.

24 Q.   I'm just asking you to confirm if that was your

25 testimony, sir?

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District of New Jersey

1   A.   That's fair.

2   Q.   And as we were going through, kind of, the factors, you

3   know, one of the things you noted is that, in your personal

4   medical decision-making, you don't take into account payments

5   that you've received from pharmaceutical companies.

6   Correct?

7   A.   Correct.

8   Q.   You don't take those into account because you don't

9   receive those payments.

10   Fair?

11 A.   Correct.

12 Q.   It's not -- it is not something that needs to be factored

13 into or accounted for or explained with respect to your

14 medical decision-making.

15   Fair?

16 A.   Correct.

17 Q.   All right.

18   So you, sir, you'd agree with me --

19   MR. WIRMANI: Can I have the ELMO, Ms. Johnson?

20 BY MR. WIRMANI:

21 Q.   You understand that in this case, that is a factor that

22 we are discussing and that is part of the evidence?

23 A.   I wasn't here to hear the evidence presented in this

24 case, but if that's what you say, then I have no reason to

25 disagree.

1 Q.   Fair enough.

2   And, sir, you'd agree with me that because it's not a

3 -- a -- it is not -- because you do not receive those types of

4 payments, when we're talking about your medical judgment and

5 the factors you consider, it's not applying to situations like

6 we see on the screen where doctors are receiving payments.

7   Correct?

8 A.   Can you say that again. I'm sorry.

9 Q.   Your medical decision-making does not include the factor

10 of doctors receiving payments.

11   Correct?

12 A.   Correct.

13 Q.   And those are the opinions that you gave the jury, so

14 they do not apply, right, in a situation where there's another

15 factor that you haven't accounted for.

16   Fair?

17 A.   I'm not following what you're asking.

18 Q.   Well, you're talking -- These are the factors that I take

19 into consideration, and this is kind of how I come to a

20 conclusion.

21   Correct?

22 A.   Correct.

23 Q.   When you're talking about the factors that you take into

24 consideration and you come to a conclusion, you are not

25 accounting for payments that you received from pharmaceutical

1   companies?

2   A.   Correct.

3   Q.   Another factor that you are not accounting for is

4   marketing contacts with pharmaceutical companies.

5   Correct?

6   A.   Correct.

7   Q.   Because, again, that's something you don't have to take

8   into account because it's not something that you -- that you

9   allow.

10   Correct?

11 A.   Correct. And I would suggest that no physicians have to

12 take that into account if they don't choose to.

13 Q.   Correct.

14   Physicians have a -- they don't have to talk to

15 pharmaceutical reps.

16   Correct?

17 A.   Correct.

18 Q.   But you understand the facts of this case involve

19 physicians that have had numerous contacts with pharmaceutical

20 representatives?

21 A.   Yeah, and I was not here to see the evidence, so I will

22 just assume that you're telling me what happened.

23 Q.   Again, when -- just to confirm, when you're describing

24 your decision-making process, this is not a factor.

25 Influenced contact with pharmaceutical companies is not a

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 1   factor that you need to account for in explaining how you

 2   exercise your medical judgment.

 3           Correct?

 4   A.   Still correct.

 5           MR. WIRMANI:  I have nothing further, Your Honor.

 6           THE COURT:  All right.  Thank you, Mr. Wirmani.

 7        Ms. Brown.

 8   (REDIRECT EXAMINATION BY MS. BROWN:)

 9   Q.   Good morning, everyone.

10        Good morning, Dr. Rosenberg.

11        Two questions for you, sir.  Your medical judgment is

12   not influenced by pharmaceutical companies.

13        True, sir?

14   A.   True.

15   Q.   And you prescribe Prezista to patients who have a lipid

16   condition.

17        True?

18   A.   True.

19           MS. BROWN:  No further questions.  Thanks.

20           THE COURT:  All right.  Thank you, Ms. Brown.

21        Doctor, you're excused from the trial.

22           THE WITNESS:  Thank you.

23           MR. WIRMANI:  Your Honor, at this time, Relators call

24   Catherine Kaucher.

25           THE COURT:  All right.  Before you call her, I am
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 1  going to give instructions to the jury.

 2       Members of the jury, during the course of this trial,

 3  it was discovered that Janssen withheld documents that were

 4  responsive to Relators' discovery requests and which Janssen

 5  was obligated to turn over well in advance of the trial.

 6  Specifically, Janssen withheld documents pertaining to

 7  allegations of another Janssen employee, Joanne Cesario,

 8  concerning Janssen's off-label promotion of Prezista and

 9  Intelence.  You are permitted but not required to infer that

10  Janssen withheld this evidence because it was unfavorable to

11  Janssen.

12       With that instruction, Mr. Wirmani, you can -- you're

13  recalling Ms. Kaucher.  Correct?

14           MR. WIRMANI:  Yes, Your Honor.

15           THE COURT:  Ms. Kaucher you can...

16           Ms. Kaucher, come on in.  I'm going to remind you

17  that you're still under oath from your prior appearance in the

18  trial.  Okay?

19           THE WITNESS:  Okay.  Thank you.

20           THE COURT:  All right.  Mr. Wirmani, when you're

21  ready to proceed with redirect examination, you may.

22           MS. BROWN:  Your Honor, before we do that, can I

23  approach for one second, please.

24           THE COURT:  You may.

25           MS. BROWN:  Thank you.
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1   (Sidebar begins at 12:45 p.m.)

2   MS. BROWN: Your Honor, I think we discussed that the

3   Court was going to instruct her not to reveal privileged

4   information. Remember we weren't supposed to tell her that?

5   THE COURT: That is a good reminder. How do I do

6   that? Do you want me to do that outside of the earshot of the

7   jury?

8   MS. BROWN: I don't mind if it's in front of,

9   Your Honor, I just -- we couldn't do it.

10   THE COURT: No, no. You're absolutely right. I want

11   to do it. I just didn't want to do anything that looks odd in

12   front of the jury. I can boot them for five minutes.

13   MR. WIRMANI: Yeah, I think outside the presence of

14   the jury. It just -- I'm going to try to stay away from it

15   anyway. I don't want to go...

16   THE COURT: I know. But I want to make sure that --

17   what can happen with a witness is, as much as you two can

18   navigate that, a witness can just say it --

19   MS. BROWN: Agreed. That's what I'm worried about.

20   We were careful not to...

21   THE COURT: And I've already made a determination

22   that the privilege has not been waived yet. I don't want to

23   put this witness in a position to change that decision. I got

24   it.

25   MR. WIRMANI: I would just say, Your Honor, you

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 1 struck the testimony, so they shouldn't consider the stuff

 2 about lawyers anyway, so I think doing it outside the presence

 3 of the jury is the most --

 4   MS. BROWN: I'll defer to the Court on it. I just

 5 feel like, to protect her, I would normally tell her, Don't

 6 reveal --

 7   THE COURT: I agree. I think you're both on the same

 8 page. I agree.

 9   MS. BROWN: Thank you, Your Honor.

10   (Sidebar was concluded at 12:46 p.m.)

11   (Open court.)

12   THE COURT: Members of the jury, I need to just

13 excuse you for about five minutes. So with that, folks, I'm

14 going to excuse the jurors for a few minutes, but be prepared,

15 and I'm going to be calling you back in a short time so don't

16 get comfortable. All right?

17   (The jury exits the courtroom.)

18   THE COURT: Folks, everyone be seated.

19   Ms. Kaucher, I just want to make sure I advise you of

20 something. In your examination that you're about to go

21 through, I want to be clear that you're not being asked to

22 divulge any communications that you've had with attorneys that

23 may be protected under the attorney-client privilege.

24   So with respect to outside counsel who may be hired by

25 Janssen to do certain things, that's not what this line of

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 1   questioning is going into.  So I don't want you to testify to

 2   anything that might infringe on communications that would

 3   normally be protected by Janssen's lawyers.

 4        Do you understand what I'm saying?

 5        THE WITNESS:  I do.

 6        THE COURT:  Okay.  And that would even include not

 7   just outside counsel, but if you had a communication that was

 8   in that same line of communication with a Janssen lawyer,

 9   somebody who's maybe even in-house, like an in-house attorney,

10   that same privilege would apply.

11        So I just want to be careful that when you're

12   questioned about conduct that is outside of those lawyer

13   communications, things like compliance and stuff.

14        Do you understand what I'm saying?

15        THE WITNESS:  I do.  May I ask a question?

16        THE COURT:  Yes.

17        THE WITNESS:  If I'm asked a question and I can't

18   answer because the answer is within that, would I just say I

19   can't respond?

20        THE COURT:  I understand.  So if you're asked a

21   question that you believe you'd have to divulge communication

22   that you had with an attorney?

23        THE WITNESS:  Yeah.  The only answer would be what I

24   know because of conversations with --

25        THE COURT:  I think that -- I think -- and,
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1   Mr. Wirmani and Ms. Brown, you can weigh in, but mine would be

2   to say, I can't respond to that question because it would

3   involve my communication with an attorney.

4   Is that not fair, Mr. Wirmani?

5   MR. WIRMANI: Yeah. I'm not sure how else she could

6   answer it.

7   MS. BROWN: I think that's the only answer.

8   THE COURT: So that's what I would want you to do. I

9   wouldn't want you to just say, I can't answer that question,

10 because that's confusing.

11   THE WITNESS: Yeah, that's why I didn't want to --

12   THE COURT: And I don't want that to be confusing to

13 the jury. I think you can say -- and I'm not so sure a

14 question will be asked of you that would involve that. But if

15 it were, you could say, I'm not sure I can answer -- I don't

16 believe I can answer that question because that would involve

17 me divulging a communication that I had with a lawyer.

18   Fair enough?

19   THE WITNESS: That's fair.

20   THE COURT: Okay.

21   MR. WIRMANI: Your Honor, and just for clarity, I

22 think the witness should understand, and I'm not instructing

23 her, I'm asking you to instruct her, that the facts are

24 divorced from the advice. Right? If she knows of facts, she

25 can testify to those facts. She doesn't have to reveal where

1   they came from.

2   THE COURT: Absolutely.

3   Ms. Brown?

4   MS. BROWN: Yeah. I'm -- yes.

5   THE COURT: Yes. And to the extent you're going into

6   something with compliance and compliance is work, that's not

7   what I'm talking about here. I'm talking about an outside

8   counsel investigation that was initially elicited in testimony

9   a week or so ago from Janssen's counsel, where you were

10   talking about outside counsels reviewing and they were doing

11   part of an investigation, all of that is off limits. I don't

12   want you to get into that.

13   But if we're talking about what compliance is doing and

14   the effort that you're all doing within your compliance

15   department, that's free rein for you to testify to.

16   THE WITNESS: That's fair.

17   THE COURT: Okay. Does that clarify it, folks? I

18   think that's the best I can do without knowing what the

19   questions are going to be, to be candid.

20   If we hit an issue -- what I'm going to tell counsel is

21   if we hit an issue, then somebody will ask to speak with the

22   Court, and we will discuss it outside the earshot of the

23   witness and the jury.

24   MR. WIRMANI: Fair enough, Judge.

25   MS. BROWN: Thank you, Your Honor. Thanks so much.

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 1              THE COURT:  All right, folks?

 2         With that, let's get the jurors back in.  I don't want

 3   them getting comfortable.

 4              THE DEPUTY COURT CLERK:  All rise.

 5         (The jury enters the courtroom.)

 6              THE COURT:  All right, folks.  We're back.  Everybody

 7   have a seat.

 8         Mr. Wirmani, when you're ready to proceed, you may.

 9         MR. WIRMANI:  Thank you, Your Honor.

10   (CATHERINE KAUCHER, HAVING BEEN PREVIOUSLY SWORN/AFFIRMED,

11   TESTIFIED AS FOLLOWS:)

12   (REDIRECT EXAMINATION BY MR. WIRMANI:)

13   Q.   Ms. Kaucher, welcome back.

14   A.   Thank you.

15   Q.   Just to reorient the jury, you testified last week in

16   this case.

17        Correct?

18   A.   Yes.

19   Q.   Okay.

20        You are a Janssen witness that Relators called in their

21   case.

22        Correct?

23   A.   Yes.

24   Q.   And --

25   A.   Yes.
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 1  Q.   -- I examined you.

 2        Correct?

 3  A.   Yes.

 4  Q.   Ms. Brown examined you?

 5  A.   Correct.

 6  Q.   Correct?

 7        And then at that point in time your testimony was

 8  suspended.

 9        Correct?

10  A.   Yes.

11  Q.   You were asked to leave but told that you would be

12  subject to recall.

13        Correct?

14  A.   Yes.

15  Q.   For our redirect examination.

16        Correct?

17  A.   Correct.

18  Q.   And you understand that today is a continuation of your

19  testimony from last week.

20        Correct?

21  A.   I do.

22  Q.   And just to kind of reorient the jury, you were the

23  compliance officer for Janssen between 2010 -- I believe

24  October of 2010 and, I think, 2015.

25        Correct?
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 1  A.   Yeah.  Around about, yeah.

 2  Q.   In that role, you had oversight of the drugs Prezista and

 3  Intelence.

 4       Correct?

 5  A.   Correct.

 6  Q.   You also had oversight of the speakers' bureau with

 7  respect to those two drugs, Prezista and Intelence.

 8       Correct?

 9  A.   Correct.

10  Q.   Okay.

11       And you understand from your preparation and from

12  examination last week that my clients, Christine Brancaccio,

13  Jessica Penelow, that they have brought allegations related to

14  off-label marketing at Janssen.

15       Correct?

16  A.   I do understand that.

17  Q.   You understand that those allegations relate to the drugs

18  Intelence and Prezista.

19       Correct?

20  A.   I do understand that.

21  Q.   You understand that the relevant time period is 2006 to

22  2014.

23       Correct?

24  A.   I do.

25  Q.   And you understand that my clients allege that that
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1   off-label marketing of those two drugs was widespread and

2   systematic throughout the company?

3   A.   I do understand the allegation.

4   Q.   You understand that my clients allege that the directions

5   to engage in that conduct were pushed down from upper

6   management to middle management to the ground-level

7   salespeople.

8   Correct?

9   A.   I understand the allegation, yes.

10 Q.   You understand that -- that part of the allegations is

11 that off-label studies and off-label information was used in

12 the field by salespeople.

13   Correct?

14 A.   I understand that allegation, yes.

15 Q.   You understand that the allegation is that that

16 information was pushed down from the tops of Janssen to the

17 ground-level salespeople.

18   Correct?

19 A.   I understand that's the allegation.

20 Q.   Yeah.

21   You understand that in particular, my clients allege

22 that their manager for a period of time, Frank Murphy, was

23 directing and encouraging them to use off-label studies and

24 materials in the sale of Prezista and Intelence.

25   Correct?

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1   A.   I understand that's their allegation.

2   Q.   Okay.

3   And you understand that they raised those allegations

4   nearly 12 years ago?

5   A.   I don't know the exact time. I apologize.

6   Q.   They filed a complaint 12 years ago that raised

7   allegations of off-label marketing of these drugs, and

8   particularly with respect to off-label studies being

9   disseminated from the company for use in the field with

10   doctors.

11   Do you understand that?

12   A.   I do understand that.

13   Q.   You understand that a complaint is the operative document

14   that starts a case. It's the -- it's the allegations that

15   start a lawsuit.

16   Do you understand that?

17   A.   I understand the allegations.

18   Q.   And you understand that in addition to those allegations,

19   they both provided testimony in this case about that conduct:

20   The receipts and the use of off-label studies.

21   Do you understand that?

22   A.   That's my understanding.

23   Q.   And do you understand that they and other witnesses have

24   testified, they're on record as saying that this information

25   came from their management and in particular, with respect to

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 1  my clients, from Frank Murphy.

 2          Do you understand that?

 3  A.   I -- I am not privy to the specific testimony that they

 4  said, but if that's what was said, then I understand what's

 5  being told to me.

 6  Q.   Okay.

 7          And you understand, ma'am, that Janssen denies those

 8  allegations?

 9  A.   I do understand that.

10  Q.   You understand that Janssen has denied those allegations,

11  and particularly with respect to dissemination and use of

12  off-label studies, since day one of this lawsuit?

13  A.   I do understand that.

14          MR. WIRMANI:  Ms. Johnson, can I have the ELMO,

15  please.

16  BY MR. WIRMANI:

17  Q.   And, ma'am, are you aware of the fact that in a

18  litigation like this, parties can serve on one another

19  something that's called a request for admission?

20  A.   Can you repeat?  I'm sorry.

21  Q.   Are you aware that in a lawsuit like this, parties can

22  serve on one another something that is called a request for

23  admission?

24  A.   I don't.

25  Q.   Okay.
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1   And are you aware of the fact that those requests for

2   admission basically asked -- they ask for an admission or a

3   denial of a particular fact that the other party is alleging

4   in the case.

5   Do you understand that?

6   A.   I do.

7   MR. WIRMANI: And, Your Honor, at this time I'd move

8   into evidence Plaintiffs' Exhibits 1860, 1861, and 1862, which

9   are the first -- the first responses to Plaintiffs' Request

10   For Production is 1860, the second responses to Defendants'

11   Request For Admission -- or Plaintiffs' Request For Admission,

12   which are 1861, and then the third response to Janssen's --

13   excuse me -- Janssen's response to Plaintiffs' Request For

14   Admission, which is 1863.

15   MS. BROWN: I have no objection to these. Thank you.

16   THE COURT: All right. So admitted.

17   (Relators' Exhibit 1860 in evidence.)

18   (Relators' Exhibit 1861 in evidence.)

19   (Relators' Exhibit 1863 in evidence.)

20   BY MR. WIRMANI:

21   Q.   Ma'am, and you can -- you can see there on the screen

22   that Janssen was asked to admit that the company, right, the

23   sales representatives used studies provided by the company,

24   which is Janssen, including the METABOLIK study and the

25   DART study, on their sales calls with doctors to promote

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1 Prezista as lipid neutral and for treatment-naive patients.

2   Do you see that statement, ma'am?

3 A.   I'm not sure the context of the document.

4 Q.   Do you see --

5 A.   Or what I'm looking at. I'm sorry.

6   THE COURT: He's just asking to see if you see that

7 statement. That's the only question.

8   THE WITNESS: Oh, okay.

9   Yes, I see the statement.

10 BY MR. WIRMANI:

11 Q.   And if you look at the answer provided by Janssen,

12 Janssen says that it denies that sales personnel used studies

13 provided by the company on their sales calls with doctors to

14 promote Prezista as lipid neutral or to promote Prezista for

15 treatment-naive patients before Prezista was approved for that

16 population.

17   Do you see that?

18 A.   I do see that.

19 Q.   Okay.

20   If we turn to page 8 of that document, there is a

21 similar statement with respect to the drug Intelence, stating

22 that Janssen is asked to admit that the company sales

23 representatives used studies provided by the company,

24 including the DeJesus study, on their sales calls with doctors

25 to promote Intelence for a once-daily dosing and for

1 treatment-naive patients.

2   Do you see that statement on the screen, ma'am?

3 A.   I do see the statement.

4 Q.   And then you can see Janssen's answer that they denied

5 those facts.

6   Correct?

7 A.   I do see this.

8 Q.   Ma'am, you also understand that -- because you were asked

9 about it -- that my clients, in connection with this lawsuit,

10 alleged that another Janssen employee named Joanne Cesario

11 raised similar allegations about off-label marketing of the

12 drugs Prezista and Intelence. You understand that.

13   Correct?

14 A.   I do, yes.

15 Q.   Are you aware of the fact that they have detailed

16 allegations in their complaint about this specific issue,

17 about Ms. Cesario raising complaints about off-label marketing

18 of the drugs Prezista and Intelence?

19 A.   I'm not aware of that.

20 Q.   Are you aware of the fact that they have testified and

21 other witnesses have testified in this case about

22 Ms. Cesario's allegations with respect to off-label marketing

23 of the drugs Prezista and Intelence?

24 A.   No, I am not aware of that.

25 Q.   Are you aware of the fact that -- that Ms. Brancaccio and

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 1  Ms. Penelow, that they allege that Ms. Cesario, similar to

 2  them, made claims that Janssen would push down off-label

 3  information in studies through middle management, including

 4  through Frank Murphy, for use in the field?

 5  A.   I am not aware of that.

 6  Q.   And are you aware of the fact that my clients allege that

 7  Janssen conducted a whitewashed investigation into

 8  Ms. Cesario's allegations?

 9  A.   Conducted a what?

10  Q.   A whitewashed investigation, a perfunctory, insufficient

11  investigation into Ms. Cesario's allegations.

12       Are you aware of that fact?

13  A.   No, I'm aware of that.

14  Q.   And are you aware of the fact that my clients allege that

15  they are aware of the fact that, after Ms. Cesario made these

16  allegations, she was at some point terminated from the

17  company?

18       Are you aware that my clients make that allegation?

19  A.   I am not.  Oh, I am.  I apologize.  I am aware of that.

20  Q.   You are aware?

21  A.   Yes.

22  Q.   And you were asked last week in your testimony specific

23  questions about your investigation into Ms. Cesario's

24  allegations.

25       Correct?
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 1   A.   Yes.

 2   Q.   Okay.

 3        I want to look at some of that testimony with you to

 4   reorient both you and the jury.

 5        Okay?

 6        MR. WIRMANI:  Ms. Johnson, if we have it, can we

 7   bring up transcript 4248?

 8        Is there a way to blow that up so it's a little bit

 9   clearer for the jury to see?

10   BY MR. WIRMANI:

11   Q.   Ma'am, this was the portion of your testimony after I had

12   asked you questions where Janssen's counsel was asking you

13   questions.

14        Okay?

15   A.   Uh-huh.

16   Q.   I want you to be aware of kind of where this took place

17   in your testimony last week.

18        Fair?

19   A.   Yes.

20   Q.   And Ms. Brown said, "Ms. Kaucher, I want to ask you some

21   questions on the topic of just your work as a compliance

22   officer as it related to Ms. Cesario's complaints to

23   compliance."

24        Do you see that?

25   A.   I do.
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1   Q.   She said, "Do you understand the nature of that

2   question?"

3   And you answered, "Just the actions that I took?"

4   She said, "Yeah."

5   You said, "In regard to the specific case?"

6   Do you see that?

7   A.   Yes.

8   MR. WIRMANI: And can we go up that a little bit, Ms.

9   Johnson.

10   BY MR. WIRMANI:

11   Ms. Brown said, "Exactly, ma'am" -- "Exactly, ma'am.

12   Just what your work in compliance was, not what other people

13   may have done. Just you."

14   Do you see that?

15   A.   Yes, I do.

16   Q.   And you were asked, "Does that make sense?"

17   And you responded, "Yes."

18   Correct?

19   A.   Yes.

20   Q.   And you were then asked, "So as I understand it, there

21   was a time when Ms. Cesario brought concerns to the compliance

22   department about potential off-label marketing. Is that

23   right?"

24   And your answer was "Correct."

25   Do you see that?

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1   A.   I do.

2   Q.   Then you were asked, "Would you just remind us what you

3   did to look into those concerns?"

4   And your response, Ms. Kaucher, was "Yes. My process

5   for any complaint brought forward would be to establish all of

6   the people that I needed to speak with who might touch the

7   particular issue." And then you go on to state "That could be

8   sales reps, sales managers, marketing, quite frankly, anybody

9   in the company I would need to speak with." And then you go

10 on to say that "I conducted direct phone calls with those

11 people."

12   Do you see that?

13 A.   I do see that.

14 Q.   You said, "I pulled data that compliance had or

15 compliance reports, and I also contacted customers as well as

16 health care providers, doctors."

17   Do you see that?

18 A.   I do see that.

19 Q.   And then Ms. Brown asked you, "By 'customers,' do you

20 mean doctors?"

21   And your response is "Yes."

22   It goes on to ask, "And what was your conclusion of

23 your work looking into those concerns?"

24   Do you see that question that you were asked,

25 Ms. Kaucher?

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 1   A.   I do.

 2   Q.   And your response --

 3           MR. WIRMANI:  If we could blow that up.

 4   BY MR. WIRMANI:

 5   Q.   You stated to this jury last week that "My conclusion of

 6   my work was that I was not able to substantiate any of the

 7   claims that she had made by any factual substance."

 8           Do you see that, ma'am?

 9   A.   I do.

10           MR. WIRMANI:  Ms. Johnson, can we go to 4235 of the

11   transcript.

12   BY MR. WIRMANI:

13   Q.   And if you look, starting at line 10, you're referring to

14   the same investigation.  You said that "I don't recall the

15   specific what was brought forward, but we immediately looked

16   into all concerns that she brought forward, did a diligent

17   investigation, which included multiple levels of my

18   organization, and we were unable to find or substantiate any

19   of the allegations that she had made."

20           Do you see that?

21   A.   I do.

22           MR. WIRMANI:  Ms. Johnson, can we go to 4236, please.

23           MS. BROWN:  Your Honor, may we approach on that,

24   please.

25           THE COURT:  You may.
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United States District Court
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 1          (Sidebar begins at 1:06 p.m.)

 2          MS. BROWN:  We're checking, Your Honor, but I believe

 3  what just went up on the screen was struck.

 4          MR. WIRMANI:  It was.

 5          MS. BROWN:  He just put struck testimony back up on

 6  the screen.

 7          MR. WIRMANI:  It's subject to impeachment.  I'm not

 8  offering it as testimony.

 9          THE COURT:  What?

10          MR. WIRMANI:  The fact that she testified that --

11          THE COURT:  But we struck the testimony.

12          MR. WIRMANI:  It can still be impeached.  It still

13  goes to her credibility.

14          MS. BROWN:  No.

15          THE COURT:  No.  If testimony is struck, it doesn't

16  exist.  I was thinking that you were going through testimony

17  that was permitted before the jury.

18          How do you ask me to strike testimony I told the jury

19  not to consider in any sort of way but then you can bring it

20  up on a cross-examination as if that's testimony before the

21  jury?  That doesn't make any sense.  But answer me.  I don't

22  want Ms. Brown speaking.

23          MR. WIRMANI:  No, I understand.  And I certainly

24  wasn't trying to violate any of the Court's orders.  My

25  thought process was that she could still be impeached on
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1 statements that she made.

2   THE COURT: Not if I struck them. You guys asked me

3 to strike that testimony, which is me instructing the jury

4 they are not to consider those statements in any sort of way.

5 Why are you asking me to strike testimony for the jury not to

6 consider, and then you're permitted to impeach her on

7 statements that don't exist? When I strike them, it's as if

8 they were never said, as if they were never spoken.

9   MR. WIRMANI: Then I would say, Your Honor, I

10 completely understand the Court's ruling. That last

11 transcript that I put up, those three lines I read, that's the

12 only thing that was part of the struck testimony. I think the

13 jury should be instructed to disregard that and --

14   THE COURT: Which part now, because I'm a little bit

15 unclear?

16   MR. WIRMANI: The last statement I read. Just that

17 very last transcript. I can bring it up, if you'd like.

18   THE COURT: Can you bring it up -- well, then you're

19 going to bring it up -- but I'm just striking that part

20 because that was stricken testimony.

21   MR. WIRMANI: Yes.

22   THE COURT: All right.

23   Objection is sustained.

24   MS. BROWN: Thank you, Your Honor.

25   MR. WIRMANI: It's the highlighted portion here.

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 1              THE COURT:  This was stricken?

 2              MR. WIRMANI:  Yes.

 3              THE COURT:  All right.  So you're going to have to

 4  put this up there, and then I am going to say -- well, you

 5  tell me how you want me to proceed.

 6              MS. BROWN:  Yeah, my concern is twofold.  Certainly,

 7  it needs to be stricken, but this entire transcript was just

 8  up on screen, so I think we need an instruction to disregard.

 9              THE COURT:  Slow down.

10              MS. BROWN:  I apologize.

11         Your Honor, I would request the prior question is

12  stricken and disregard the testimony that was just displayed.

13              THE COURT:  Just the prior question, right,

14  Mr. Wirmani?

15              MR. WIRMANI:  Your Honor, I'm looking at the

16  transcript now.  I just want to make we're on -- you say,

17  Folks, just a quick instruction.  I'm going to strike

18  questions and testimony regarding anything regarding the

19  investigation that the witness just referred to.  You go on to

20  specify so anything regarding an investigation or any findings

21  of a particular investigation are struck, and you are not to

22  consider that testimony.

23              THE COURT:  This relates to the investigation?

24              MR. WIRMANI:  Yeah, I think Mr. Marketos is not

25  correct about that.
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1   THE COURT: Yeah, so here's what I propose, and,

2   Ms. Brown, I believe you're in agreement.

3   MS. BROWN: Yes.

4   THE COURT: I'm going to strike the last question and

5   the last response. I don't think you need to put it up again,

6   because I'm presuming you don't want it put up a second time.

7   MS. BROWN: I do not, and could the Court say, And

8   disregard what was displayed on the screen --

9   THE COURT: As part of that response.

10   MS. BROWN: Yes.

11   THE COURT: It's just --

12   MS. BROWN: Thank you.

13   THE COURT: Just to be clear, last question, last

14   response, and what was displayed with the response.

15   MS. BROWN: Thank you, Your Honor.

16   (Sidebar was concluded at 1:10 p.m.)

17   (Open court.)

18   THE COURT: All right. The objection is sustained.

19   So just the last question and last response and the

20   last transcript with that response is stricken. So you are

21   just not to consider that -- that last question and response

22   and display. All right, folks? As if it didn't happen.

23   And like I've said throughout the trial, if I strike

24   something, you're not to consider it in any way. It's as if

25   it's not part of your deliberations, as if it's not evidence

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 1   in the case.

 2          But, Mr. Wirmani, you can proceed when you're ready.

 3             MR. WIRMANI:   Thank you, Your Honor.

 4          And can we have the ELMO back, Ms. Johnson.

 5   BY MR. WIRMANI:

 6   Q.   Ms. Kaucher, just to reconfirm, before that last question

 7   which the judge addressed, you told this jury in your

 8   testimony last week that my conclusion of my work was that I

 9   was not able to substantiate any of the claims that she made

10   by any factual substance.

11          And you're referring to Ms. Cesario.

12          Correct?

13   A.   Yes.

14   Q.   Now, just to summarize what we looked at.  You told this

15   jury last week that you conducted an investigation.

16          Correct?

17   A.   I did.

18   Q.   Okay.

19          You told the jury that you identified the people that

20   you needed to speak to.

21          Correct?

22   A.   Yes.

23   Q.   You told the jury that you conducted direct phone calls

24   to the people you identified.

25          Correct?
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 1  A.    That is what I recall, yes.

 2  Q.    You said that it included anybody that you needed to

 3  speak to.

 4         Correct?

 5  A.    Yes.

 6  Q.    You listed a number of different types of parties:  sales

 7  reps, managers, doctors.

 8         Correct?

 9  A.    I did, yes.

10  Q.    You said you pulled data and compliance reports.

11         Correct?

12  A.    Yes.

13  Q.    And you told the jury last week that after conducting

14  that investigation, you could not substantiate any of

15  Ms. Cesario's allegations.

16         Correct?

17  A.    That's what I recall.

18  Q.    Ms. Kaucher, that testimony that you gave last week to

19  this jury, that was false, wasn't it?

20  A.    Not that I recall.

21  Q.    You understand, ma'am, that when we were questioning you

22  last week, we did not have the documents associated with your

23  investigation.

24         Are you aware of that?

25  A.    I am not.
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1   Q.   Did you know that those documents were requested from

2   Janssen years ago?

3   A.   I am not aware of that.

4   Q.   Did you know specific documents were requested regarding

5   the allegations that Ms. Cesario made?

6   A.   I don't specifically recall.

7   Q.   Did you know that Janssen represented years ago that

8   after a diligent search, which included the health care

9   compliance files, that they could not locate relevant

10 documents?

11 A.   I'm not aware of what they said.

12 Q.   Did you know that since your testimony last week, we,

13 myself, my clients, have learned that Janssen withheld the

14 documents related to Ms. Cesario's allegations and your

15 alleged investigation?

16 A.   I am not aware of that.

17 Q.   Are you aware of the fact that the Court ordered them to

18 go look for the documents again, years later, and that they

19 were located within a matter of days and turned over to us?

20 A.   I am partially aware, but I don't know the full extent.

21 Q.   You are aware of the fact that we now have those

22 documents?

23 A.   I -- I am not aware. I don't know what specifically

24 happened.

25 Q.   Let's take a look, and we'll see if your testimony last

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 1 | week was truthful.

 2 |       Okay?

 3 | A.   Okay.

 4 |        MR. WIRMANI:   Can we bring up just for the witness

 5 | and the lawyers Plaintiffs' Exhibit 1854, please.

 6 | BY MR. WIRMANI:

 7 | Q.   Ma'am, do you see on the screen there an Investigation

 8 | Summary Report?

 9 | A.   I'm sorry?

10 | Q.   Do you see there on the screen an Investigation Summary

11 | Report?

12 | A.   I do.

13 | Q.   Okay.

14 |       And you see the date of that report is February 4th of

15 | 2011.

16 |       Correct?

17 | A.   I do.

18 | Q.   Okay.

19 |       You see that the complainant is a Ms. Joanne Cesario.

20 |       Correct?

21 | A.   I do.

22 | Q.   And that the operating company is Tibotec.

23 |       Correct?

24 | A.   Yes.

25 | Q.   And that the subjects of the investigation are Frank
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 1  Murphy and Nancy Peterson, correct?
 2  A.   I do see that.
 3         MR. WIRMANI:  Your Honor, at this time we would move
 4  to admit Relators' Exhibit 1854 into evidence.
 5         MS. BROWN:  No objection, Your Honor.
 6         THE COURT:  So admitted.
 7  (Relators' Exhibit 1854 in evidence.)
 8  BY MR. WIRMANI:
 9  Q.   And, ma'am, what you see there on the screen is an
10  investigation by the ERLR Specialist Group.
11        Are you familiar with that group?
12  A.   Yes.
13  Q.   Okay.
14        What is the ERLR Specialist Group?
15  A.   Equivalent to human resources.
16  Q.   Okay.
17        Is that a division within Janssen, or is it an outside
18  third party?
19  A.   J&J does have the ERLR.  I just am unclear, this very
20  specific header, if it's a reference to anything else.
21  Q.   You see the ERRG rep is Andrea Morganelli.
22        Do you see that?
23  A.   Yes.
24  Q.   Do you know Ms. Morganelli?
25  A.   I do not.
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1 Q.   It says down there at the bottom, "BBHR, Delores Smith."

2 Do you know a Ms. Smith?

3 A.   I do.

4 Q.   Okay.

5   What does BBHR stand for, if you know?

6 A.   I believe it's business-based human resources.

7   THE COURT: Okay.   So she would have been a human

8 resources employee of Janssen?

9 A.   Yeah.   A J&J employee, yes.

10 Q.   But you're not familiar with Ms. Morganelli?

11 A.   I am not.

12 Q.   Okay.

13   And if you look there, it says, "Complaint category:

14 health care compliance violations."

15   And you see that, correct?

16 A.   I do see that.

17   MR. WIRMANI: Can we go down that document just a bit

18 and look at that first paragraph.

19 BY MR. WIRMANI:

20 Q.   And there's a title there, "Investigation Background."

21   Do you see that?

22 A.   I do.

23 Q.   And it goes on to say that "Joanne Cesario is a senior

24 virology sales specialist with Tibotec."   It says, "Cesario

25 sells Prezista and Intelence to health care practitioners in

1   central New Jersey."

2   Do you see that?

3   A.   I do.

4   Q.   And it says, "In August of 2010, Cesario informed Delores

5   Smith that Frank Murphy, her district manager, and Nancy

6   Peterson, her key account manager, had engaged in health care

7   compliance violations and HR violations."

8   Do you see that?

9   A.   I do.

10 Q.   It goes on to say that "Smith forwarded the matter to

11 ERRG for investigation."

12   Do you see that?

13 A.   I do.

14 Q.   Again, is ERRG -- is that Janssen, or is that a third

15 party?

16 A.   I am not sure.

17   MR. WIRMANI: Can we go to the last sentence. And

18 we're going to take a look at these allegations in more

19 detail, but can we go to the last sentence of that first

20 paragraph, please.

21   The very last sentence, Ms. Johnson. I guess the last

22 paragraph on the page.

23   Thank you.

24 BY MR. WIRMANI:

25 Q.   It says that "ERRG contacted Tim Grimes," right,

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1 "director of health care compliance regarding Murphy and

2 Peterson's alleged health care compliance violations."

3   Do you see that?

4 A. I do.

5 Q. Who is Tim Grimes?

6 A. He was my boss's boss at the time.

7 Q. Okay.

8   So Mr. Grimes is two levels above you?

9 A. Correct.

10 Q. What is his position?

11 A. What, what?

12 Q. What was his position, ma'am?

13 A. His position? He was senior director of health care

14 compliance.

15 Q. It says that "On September 1st of 2010, Cesario met with

16 Grimes in the ERRG. And Cesario reiterated her allegations to

17 Grimes, and Grimes commenced an investigation in partnership

18 with ERRG."

19   Do you see that?

20 A. I do.

21   MR. WIRMANI: Let's go to page 2 of that document,

22 please.

23 BY MR. WIRMANI:

24 Q. And if you look under "investigation," it says that

25 "Health care compliance led the investigation" and that

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 1  Grimes" who you just told us was your boss's boss, "and the

 2  ERRG interviewed the following individuals in furtherance of

 3  the investigation."

 4          Do you see that?

 5  A.   I do.

 6          MR. WIRMANI:  Can we go to page 3 of that document,

 7  please.

 8  BY MR. WIRMANI:

 9  Q.   Now, just to be clear, Ms. Kaucher, you were asked last

10  week, and you gave pretty detailed testimony about your

11  investigation into these allegations.  You told this jury that

12  you could not substantiate any of the allegations.

13          Correct?

14  A.   That's correct.

15          MR. WIRMANI:  Let's take a look at allegation number

16  3.

17          Thank you.

18  BY MR. WIRMANI:

19  Q.   Allegation number 3, Ms. Cesario said that "At a district

20  meeting in June, Murphy," who is Frank Murphy, "and Peterson,"

21  who is Nancy Peterson, "distributed unapproved sales aids to

22  the sales reps without a disclaimer or directive that they are

23  for training purposes only and not for distribution to health

24  care practitioners."

25          Do you see that?
```

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1   A.   I do.

2   Q.   What is the finding that this investigation made with

3   respect to that allegation?

4   A.   I do see that.

5   Q.   I'm asking you: What is the finding, ma'am?

6   A.   Oh, what is the finding. I'm sorry.

7   The finding says, "This allegation is substantiated."

8   Do you want me to keep reading?

9   Q.   So this allegation of Ms. Cesario that -- unapproved,

10   right, unapproved sales aids that were made available to the

11   sales staff by Frank Murphy, this investigation sustained that

12   allegation.

13   Correct?

14   A.   That's what I'm reading.

15   Q.   And it says that "Murphy and Peterson admitted that they

16   failed to expressly direct the sales reps at the meeting not

17   to distribute some of the educational materials to health care

18   practitioners."

19   That's what HCP stands for.

20   Correct?

21   A.   Correct.

22   Q.   Okay.

23   So Murphy and Peterson don't even deny. They admit

24   that they were providing the stuff to sales staff without any

25   direction that it be used for internal purposes only.

1   Correct?

2   A.   I see that.

3   Q.   And you understand that those allegations mirror

4   allegations that my clients have made in this case?

5   A.   I don't agree with that.

6   Q.   You understand that they mirror allegations that my

7   clients have made specifically with respect to Frank Murphy?

8   A.   I am -- I don't know what allegations they've made

9   specific to Frank Murphy, so I can't speak to that.

10   Q.   It goes on to say that, notwithstanding all of the sales

11   reps, except for Cesario, they all stated that they were aware

12   of the restrictions on the distribution of the material and

13   that neither Murphy nor Peterson had to provide them

14   directions.

15   Do you see that?

16   A.   I do.

17   Q.   So basically a violation is found, substantiated, that

18   unapproved, right, sales aids, sales aids that aren't supposed

19   to be distributed and used in the field, are being handed out

20   by management, and the investigation concludes, well,

21   everybody knows they're not supposed to use them, so it's

22   okay.

23   A.   I apologize. What is your question?

24   Q.   The investigation concludes that unapproved materials are

25   being distributed by management to the sales force, that there

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 1  is no disclaimer, no direction, that is not supposed to be

 2  used in the field, and the investigation says, well, we talked

 3  to people, and they said they knew they weren't supposed to

 4  use them so -- and that's where the investigation into that

 5  allegation ends.

 6       Correct?

 7  A.   What I read is that it said that all of the sales reps

 8  were aware of the restrictions except for Cesario.

 9  Q.   And --

10  A.   And that neither Murphy or Peterson had provided them

11  directions.

12  Q.   Are you aware of the fact, ma'am, that Ms. Penelow

13  testified to these very facts in this case and testified about

14  how the sales force banded together -- or Ms. Donna Graham

15  also maybe testified.  I can't recall between the two, but I

16  don't want to misrepresent it -- but there's been testimony in

17  this case that the sales folks banded together to save Frank

18  Murphy?

19  A.   This is the first I'm hearing that.

20       MR. WIRMANI:  Can we go to page 3 of the report,

21  please.  Excuse me.  Allegation.  Put that back down.

22  BY MR. WIRMANI:

23  Q.   Do you recall what Murphy's punishment for this was?

24  A.   I do not.

25  Q.   Was he terminated?
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1   A.   I do not recall his punishment, I should say.

2   Q.   Was he suspended without pay?

3   A.   I do not recall.

4   MR. WIRMANI: Let's bring up Plaintiffs' Exhibit 1856

5   just for the witness and counsel.

6   BY MR. WIRMANI:

7   Q.   And I'll try to refresh your recollection.

8   Ma'am, do you see there on the screen a memorandum to

9   Mr. Murphy from Mr. Iacobellis, who is the head of sales?

10 A.   I do see this.

11 Q.   The date there is February 17th, 2011.

12   Correct?

13 A.   I do see this.

14 Q.   And the reply there is "verbal warning."

15   Do you see that?

16 A.   I do.

17   MR. WIRMANI: Your Honor, at this time, we move to

18 admit Relators' 1856 into evidence.

19   MS. BROWN: No objection, Your Honor.

20   THE COURT: So admitted.

21   (Plaintiffs' Exhibit 1856 in evidence.)

22   MR. WIRMANI: Can we -- thank you, Ms. Johnson.

23 BY MR. WIRMANI:

24 Q.   Mr. Murphy says, "As a result of an investigation, a

25 violation of Tibotec Therapeutics' policy on the process for

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 1   submitting articles for educational/journal club purposes was

 2   identified in conjunction with execution of your job

 3   responsibilities."

 4        Do you see that?

 5   A.   I do.

 6   Q.   Now, when we're talking about articles that are supposed

 7   to be only educational or used in the journal club process,

 8   we're talking about off-label articles.

 9        Correct?

10   A.   I don't know specifically what the journals were, so I

11   can't say that they were or were not.

12   Q.   Okay.

13        The principle issue and concern about unapproved

14   materials being used in the field, that would deal with

15   off-label information.

16        Correct?

17   A.   Not necessarily.

18   Q.   Ma'am, do you have a reason to believe this is something

19   other than off-label information that Mr. Murphy was handing

20   out to the sales force?

21   A.   I don't know what it was, so without seeing exactly what

22   it was, I can't opine on whether it was on or off-label.

23   Q.   Are there restricted on-label materials that -- that,

24   say, for educational purposes that the company was concerned

25   about being used in the field?
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1   A.   There could be.

2   Q.   What on-label materials would the company be concerned

3   about being used in the field?

4   A.   There could be an on-label study in which we give only a

5   component to the sales reps which would be approved through

6   our company review process.

7   Q.   But they have the entire label?

8   A.   There may be components of the clinical trial not

9   specifically in the label, albeit still an on-label study,

10   which is why we would have the reps follow specifically what

11   was company approved only.

12   Q.   Ms. Kaucher, you told the jury last week that you did

13   this investigation?

14   A.   I did.

15   Q.   Okay.

16   So you don't remember what the materials were?

17   A.   From 13 years ago, not specifically.

18   Q.   And did you look at that report that we just looked at?

19   Did you realize that your name isn't noted nowhere in that

20   investigation report?

21   A.   I was specifically asked by Tim Grimes to investigate

22   something, for which I did do that. I do not know if there

23   were other investigations also going on at that same time that

24   I may not have been privy to, as he was my boss's boss.

25   Q.   Are you claiming this is a different investigation than

1 the one --

2 A.   I do not know. I do not know. I know that I was

3 asked --

4 Q.   And where --

5   THE COURT: Guys, folks, sorry. One at time.

6   You have to wait for the question to be asked before

7 you respond, ma'am.

8   THE WITNESS: Sorry.

9 BY MR. WIRMANI:

10 Q.   Are you telling this jury that there was a separate

11 investigation that you did, separate and apart from the one

12 that your counsel turned over to us and represented was the

13 investigation you testified about last week?

14 A.   I don't know if this was separate or not. I know that

15 Tim Grimes asked me to look into specifics, which I cannot

16 recall this exact instance what they were, and I did do these

17 things, and I reported back to him that I had not found

18 anything, that I recall.

19 Q.   So you did the investigation, reported back to Mr. Grimes

20 that you cannot substantiate anything, and now we're looking

21 at a report that substantiates multiple allegations?

22 A.   I can only speak to what I was asked to do, and I did

23 what I was asked to do, and that's what I replied back to him

24 with.

25 Q.   Ma'am, last week you said that you interviewed the

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1 people, you interviewed the doctors, you made the conclusions,

2 you could not find anything. You said that was the -- your

3 health care compliance investigation.

4   Are you claiming that it was separate from this

5 investigation?

6 A.   I do not know if it was. I could only speak to what I

7 was asked to do, and that's what I was asked to do by Tim

8 Grimes. He brought forward what the allegation was to me and

9 said, Please look into this, for which I did.

10 Q.   What were the allegations that you were asked to look

11 into?

12 A.   I could not say specifically. It was a very long time

13 ago, and I have honestly not looked much at it since

14 probably 2011. I can't regurgitate the specifics.

15   MR. WIRMANI: Ms. Johnson, can we bring up

16 Plaintiffs' Exhibit 1853. Just for the witness and counsel.

17   It should be 1852. I apologize.

18 BY MR. WIRMANI:

19 Q.   Ma'am, does that appear to be an email from a Bryan

20 O'Dea, to you?

21 A.   I do see this.

22   MS. BROWN: Your Honor, I object as I think counsel

23 misspoke regarding the document.

24 BY MR. WIRMANI:

25 Q.   From you to Mr. O'Dea. Is that an email from you to

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 1  Mr. O'Dea?

 2  A.    I do.

 3  Q.    Okay.

 4        And the date there is 11/12 of 2010.

 5        Do you see that?

 6  A.    I do.

 7             MR. WIRMANI:  Your Honor, at this time, we move to

 8  admit 1852 into evidence.

 9             MS. BROWN:  No objection.

10             THE COURT:  All right.  So admitted.

11          (Plaintiffs' Exhibit 1852 in evidence.)

12  BY MR. WIRMANI:

13  Q.    Ms. Kaucher, as you can see there on the screen, this --

14  I'll represent to you this is the only document that your

15  counsel provided to us that shows any involvement by you in

16  this investigation.

17             MS. BROWN:  Your Honor, I object.

18             THE COURT:  Sidebar.

19             (Sidebar begins at 1:31 p.m.)

20             MS. BROWN:  The document he just put up on the screen

21  by mistake was the document that came from her computer that

22  she didn't look at.  So by mistake he put up 1853.  That's

23  from her computer.

24             MR. WIRMANI:  Well, it doesn't mention her name.

25             THE COURT:  That's not what he said.  He didn't say
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 1   where it came from.  So this is the only document that we see

 2   on the face that identifies you in this investigation.

 3           MS. BROWN:  We, I think, specifically told you we

 4   pulled the document from her computer.

 5           THE COURT:  That has nothing to do with the question.

 6   He didn't ask, None of these documents ever came from your

 7   computer.  He's looking at multiple documents.

 8        Aren't you asking, This the only document that has your

 9   name in it related to this investigation?

10           MR. WIRMANI:  Right.

11           THE COURT:  There's nothing about that.

12           MS. BROWN:  Okay, Your Honor, I understand.  It seems

13   like a misrepresentation.  He knows there's a list of

14   interviews that came from her computer.  She has a list of

15   everybody's phone number who was interviewed on her computer.

16           THE COURT:  That's proof that she conducted this

17   investigation.  Ms. Brown, you have an investigation report

18   that says "Grimes."

19           MS. BROWN:  Correct --

20           THE COURT:  It says Grimes interviewed all these

21   people.  So either nobody knows what they're doing, they're

22   lying in investigation reports, or she conducted all the

23   interviews and Grimes took credit for it.  I mean, he is

24   allowed to question them.  These documents, just to be clear,

25   Janssen turned over connected to her testimony.  This isn't
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1   some separate investigation. Right? She testified to an

2   investigation she conducted at compliance, and Janssen is

3   representing that these are the documents for that

4   investigation.

5   MS. BROWN: I understand, Your Honor.

6   THE COURT: He's allowed to question her about it.

7   All right.

8   MS. BROWN: Okay. All right. I understand. Thank

9   you.

10   (Sidebar was concluded at 1:32 p.m.)

11   (Open court.)

12 BY MR. WIRMANI:

13 Q.   Again, Ms. Kaucher, I'll represent to you that of the

14 documents that were turned over to us last week, that your

15 counsel represented was the investigation that you testified

16 about, that is the only document that contains your name.

17   Are you aware of that?

18 A.   I am not.

19 Q.   Okay.

20   And the only thing, ma'am, that you are doing on this

21 document is setting up, right, interviews?

22   You go on to say, "Dear, Bryan O'Dea.

23   Health care compliance and HR are conducting an

24 investigation and need to speak with you on Tuesday, November

25 16th of 2010 at 2 p.m."

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 1            Do you see that?
 2   A.   I do.
 3   Q.   Okay.
 4            MR. WIRMANI:  You can take that down.
 5   BY MR. WIRMANI:
 6   Q.   Now, ma'am, I just -- we've got to get this clear.  Okay?
 7            You said last week there were allegations made by
 8   Ms. Cesario regarding off-label marketing and other
 9   allegations that were brought to you.
10            Do you recall that?
11   A.   They weren't brought specifically to me, but I was asked
12   by Tim Grimes to investigate the allegation, yeah.
13   Q.   You were asked by Tim Grimes to investigate the
14   allegations, and we see Mr. Grimes' name on this report.
15            Correct?
16   A.   I do.
17   Q.   That report that we looked at, that deals with
18   allegations made by Joanne Cesario, doesn't it?
19   A.   I'm sorry, repeat.
20   Q.   That report that we looked at with Mr. Grimes' name on
21   it, it deals with allegations made by Joanne Cesario.
22            Correct?
23   A.   Yes.
24   Q.   It appears from that email we just looked at that you
25   were setting up interviews for that investigation, doesn't it?
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 1 A.   I -- I don't recall specifically.

 2 Q.   And you told this jury last week that you conducted the

 3 investigation.

 4   Correct?

 5   And are you now saying you think that you conducted a

 6 different investigation than the one Janssen's lawyers say

 7 that you were testifying about?

 8 A.   I know that Tim Grimes came to me and asked me to

 9 investigate specific things, for which I did, and I reported

10 back to him what my findings were.

11 Q.   Okay.

12   That sounds a lot like this investigation, doesn't it?

13 A.   It may. I am not sure.

14 Q.   Do you think Mr. Grimes would have been in the habit of

15 delegating an investigation to you, having you complete the

16 investigation, and then going out and conducting his own

17 investigation?

18 A.   I don't know specifically what he did or did not do. I

19 know what he asked me to do, and I know what I did.

20 Q.   Okay.

21   And what it appears you did send was out an email

22 scheduling an interview for an investigation where the report

23 refers to Tim Grimes and the ERRG Group.

24   Correct?

25 A.   Yes.

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 1   Q.   When you prepared for your testimony before last week,

 2   did you look at any documents, ma'am?

 3   A.   I did.

 4   Q.   Did you look at any documents related to the

 5   investigation into Joanne Cesario?

 6   A.   I don't recall if I did.

 7   Q.   You don't recall if you did?

 8   A.   I really don't.

 9   Q.   Do you recall looking at any of the documents we're

10   looking at today?

11   A.   I do not recall all of those, no.

12   Q.   It's kind of funny.  You had a very specific recollection

13   last week of the things you did, the types of people you spoke

14   to, and you were confident that the allegations weren't

15   substantiated.

16        But now you don't seem to remember much about the

17   logistics or what you did or how it matches up with the

18   documents, ma'am.

19        Can you explain that?

20   A.   No, that's not true.

21        I very specifically got a request from Tim Grimes to

22   investigate an allegation with Joanne Cesario, for which I

23   recall I did, and I recall reporting back to him that I was

24   unable to find something.

25   Q.   And if you conducted an investigation, you would have
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 1   documented the investigation.

 2        Correct?

 3   A.   I don't recall if I did or I didn't.

 4   Q.   Ma'am, the standard procedure in health care compliance,

 5   if you were doing an investigation that you were personally

 6   doing with interviews and pulling data, would be to have

 7   documentation of what you did.

 8   A.   I -- I don't recall if I did or did not.  It was a very

 9   long time ago.

10   Q.   Do you agree with me that that would have been the

11   standard procedure for conducting an investigation in health

12   care compliance?

13   A.   Standardly, I would have.

14   Q.   Okay.

15        Do you have any reason to believe that you did not

16   conduct your job appropriately and keep documentations of the

17   investigation that you claim you conducted?

18   A.   I do not.

19   Q.   Okay.

20        So you testified last week what you're saying is

21   completely off your own memory.

22        Is that fair?

23   A.   Yes.

24   Q.   Okay.

25        You said you testified completely off your own memory.
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1   You remember doing this investigation. It's standard

2   procedure to create documentation.

3   Correct?

4   A.   Yes.

5   Q.   You have no reason to believe that you would have

6   deviated from standard procedure for this particular

7   investigation, do you?

8   A.   I don't specifically recall.

9   Q.   And then we asked your counsel -- and, in fact, the judge

10   orders your counsel, to turn over the underlying documents for

11   the investigation that you told the jury about.

12   Are you aware of that?

13   A.   Repeat the question. I'm sorry. I want to make sure I

14   understood it specifically.

15   Q.   Following your detailed testimony about the investigation

16   that you conducted 12 years ago that you said that you

17   testified to completely from your memory, without looking at

18   any documents beforehand, without having any documents up

19   there, you testified to that investigation -- after your

20   testimony, right, the judge ordered Janssen to turn over the

21   documents related to your investigation.

22   Are you aware of that?

23   A.   I am.

24   Q.   Okay.

25   These are those documents that I am walking through

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 1  with you.

 2         Do you understand that?

 3  A.   I am not aware of them.  I did not look at the documents.

 4  Q.   In the final investigation report, right, into the same

 5  allegations that you say you investigated at the direction of

 6  Mr. Grimes, who appeared in the report, that final

 7  investigation report does not mention your name, Ms. Kaucher.

 8         Are you aware of that?

 9  A.   The final investigation does not.

10  Q.   That final investigation report -- we're going to

11  continue to look at -- doesn't mention your name.

12  A.   I am also okay with that.  Tim was my boss's boss.  And

13  like I said, I provided him the information that I had

14  investigated, and I had not found anything.  So I supplied him

15  that information.

16  Q.   Let's keep looking through this, Ms. Kaucher.

17         MR. WIRMANI:  Let's go back to Exhibit 1854,

18  Ms. Johnson.

19         And can we go to page 4 of that document.

20         Actually, page 3, Ms. Johnson.

21  BY MR. WIRMANI:

22  Q.   Allegation number 4 there -- let me start here.

23         Are you aware of the fact that there has been witness

24  after witness in this case that has testified about the

25  pressure that they were under as salespeople?
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1   A.   I am not.   I am not aware of what all the witnesses said.

2   Q.   Are you aware of the fact that witnesses have said that

3   the forecasts for the drug Prezista included off-label sales

4   and was pushed down into their sales requirements?

5   Are you aware of that fact?

6   A.   I'm only aware of it because I believe you told it to me

7   last week.

8   Q.   Okay.

9   And they testified that that created immense pressure

10   on them, which management fueled by directing them to go in

11   the field and sell off-label.

12   Are you aware of that?

13   A.   No.

14   Q.   Are you aware of the fact that people have testified that

15   the pressure was so great to increase numbers to make metrics

16   look better that people were forging MIRs?

17   Are you aware of that?

18   A.   I am not aware of their testimonies. I haven't seen

19   them.

20   Q.   Ms. Peterson -- one of the allegations that Ms. Joanne

21   Cesario made was that Peterson, Nancy Peterson, had falsified

22   calls to health care practitioners.

23   Do you see that?

24   A.   I do.

25   Q.   And, again, ma'am, this allegation of Joanne Cesario was

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 1   sustained by the health care compliance investigation.

 2   Correct?

 3   A.   That's what it says, that this allegation was

 4   substantiated.

 5   Q.   So substantiated.

 6   Correct?

 7   A.   That's what it says, yes.

 8   Q.   That means it happened. There was evidence that it

 9   occurred.

10   Correct?

11   A.   That's what I would assume so, yeah.

12   Q.   Okay.

13   The opposite of what you told the jury about

14   Ms. Cesario's allegations last week.

15   A.   I am not aware that her allegation was against Nancy

16   Peterson specifically.

17   Q.   You're aware that Ms. Cesario made allegations of

18   off-label marketing and other improper conduct by management

19   in the company.

20   Correct?

21   A.   I was aware that her allegation was off-label marketing,

22   yes.

23   Q.   Okay.

24   A.   But this says falsifying calls.

25   Q.   Ma'am, you were aware -- you testified that you were the

1   one who investigated Ms. Cesario's allegations last week.

2   That's what you told the jury.

3   A.   I investigated what Tim Grimes asked me to investigate,

4   for which I did, for which I did not find any -- any

5   validation of -- of what he asked me to investigate.

6   Q.   Okay.

7   But the report -- the only documentation we have about

8   Ms. Cesario's allegations, you don't dispute that it says that

9   her allegations, in part, were substantiated?

10   A.   I see that it says here her allegations against Peterson

11   falsifying calls are substantiated.

12   Q.   Okay.

13   It says that "Cesario alleged that she knew" -- that

14   "Ms. Cesario alleged that she knew that Peterson had falsified

15   at least one call to Dr. Casey, and she claimed that she knew

16   that because while reviewing Peterson's call notes, she

17   noticed that Peterson had logged a call to Dr. Casey on a day

18   that Cesario knew Dr. Casey was not in the office."

19   Do you see this?

20   A.   I do see that.

21   Q.   Okay.

22   And then when questioned, Peterson denied it.

23   Correct?

24   Do you see that?

25   A.   Repeat your question. I'm sorry.

1   Q.   "When questioned, Peterson said she was unable to recall

2   whether or not she had actually saw Dr. Casey on the day in

3   question."

4   Do you see that?

5   A.   I do see that.

6   Q.   Okay.

7   And then it says that "Grimes confirmed with Dr. Casey

8   that she," Peterson, "was not in her office on the day in

9   question."   Or that she, Dr. Casey, was not her office on the

10 day in question.

11   Do you see that?

12 A.   I do see that.

13 Q.   And then --

14   MR. WIRMANI: If you leave --

15 BY MR. WIRMANI:

16 Q.   There's a conversation with Ms. Peterson herself, and

17 Ms. Peterson says in that very last line of allegation 4,

18 she -- there's a record that she stated that "Everyone else

19 has always done this."

20   Do you see that?

21 A.   I do see that.

22 Q.   So Ms. Peterson tells the investigators that, having been

23 caught falsifying call records, she says that "Everyone else

24 has always done this."

25   Do you see that?

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 1   A.    I see that she said that.

 2   Q.    Okay.

 3         What investigation, if any, was conducted into her

 4   allegations that everybody else was always doing this?

 5   A.    I don't specifically recall.

 6   Q.    Do you have any evidence or reason to believe an

 7   investigation was conducted into it?

 8   A.    I don't -- I honestly don't recall.

 9   Q.    Do you recall whether Ms. Peterson was terminated?

10   A.    I don't recall.

11   Q.    Do you recall if she was punished in any way?

12   A.    I don't recall.

13         MR. WIRMANI:   Can we go to allegation number 6 on

14   page 4, Ms. Johnson.

15   BY MR. WIRMANI:

16   Q.    If you look there at allegation number 6, the report

17   claims that Ms. Cesario said that the method used to

18   compensate Tibotec's sales reps is unfair and under review.

19   However, Mr. Murphy does not want her to complain about it.

20         Do you see that?

21   A.    I do.

22   Q.    So I guess she's saying that these -- the comp method is

23   unfair, and that's what this is representing, and that

24   Mr. Murphy is telling her not to complain about it, and that's

25   the allegation this report says Ms. Cesario is making.
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1   Correct?

2   A.   That's what I read.

3   Q.   And the -- the resolution -- it says that, "During the

4   investigation, Cesario stated that the method in which the

5   company compensates sales reps for the sale of Intelence is

6   currently under review."

7   So Cesario stated this. Cesario alleged that Murphy

8   directed her to stop complaining about the compensation scheme

9   because her numbers looked better if they stick with the

10   current model.

11   Do you see that?

12   A.   I do see that.

13   Q.   And if you look at that last sentence -- or the second to

14   last sentence, ultimately what the investigation concludes is

15   that Cesario's complaints are irrelevant to the implementation

16   of any particular model or form of compensation.

17   Do you see that?

18   A.   I do.

19   Q.   And they say that because the compensation models are

20   designed and implemented by Tibotec sales, compensation team,

21   human resources, and the business leaders.

22   Do you see that?

23   A.   I do.

24   Q.   So basically this report says that her allegations about

25   the compensation system, which aren't specifically recorded in

1   that report, are basically irrelevant because the compensation

2   system is formulated by the compensation team, human

3   resources, and business leaders.

4   Correct?

5   A.   Repeat your question again. I want to make sure I

6   understand it.

7   Q.   So in that allegation, Ms. Cesario complains about the

8   compensation system.

9   Correct?

10   A.   I do see that.

11   Q.   There's no specific details about what in particular she

12   is complaining about.

13   Do you agree with me?

14   A.   From what I can see, agreed.

15   Q.   The conclusion of the report is basically that her

16   complaints are just irrelevant to the compensation system

17   because it is a system that is created by the comp team, human

18   resources and business leaders.

19   Do you see that?

20   A.   I do say -- I see that it says that.

21   Q.   Okay.

22   So just to make sure we're all on the same page,

23   Ms. Cesario raises allegations about the compensation system.

24   Those allegations are not specifically recorded in this final

25   investigation report and the response from Janssen's

1   investigation is basically, Your allegations are irrelevant,

2   none of your business because the comp team, human resources

3   and business leaders, we're the ones who put together the comp

4   plan?

5   A.   The first statement I see is "The allegation is

6   unsubstantiated," so I would assume that to mean that they

7   looked into it and whatever her allegation was was unable to

8   be verified. That's the first part that I see.

9   Q.   There's no discussion of looking into the allegations in

10 here, is there, ma'am?

11 A.   I do not know how specifically it was investigated.

12 Q.   Ma'am, my question is are there -- in that investigation

13 report, is there a discussion of them actually looking into

14 the allegations related to the comp plan?

15 A.   I don't know. I haven't -- I'd have to read it.

16 Q.   Read Allegation Number 6 to yourself, and you can tell me

17 when you're ready.

18 A.   I would have to assume that if it's saying that it's

19 unsubstantiated that they indeed looked into it.

20 Q.   Is that the way that Janssen would normally conduct

21 investigation reports? They would come to conclusions but not

22 record what investigation they did?

23 A.   This appears to be what HR did, so I am not entirely sure

24 what process they used.

25 Q.   Every other one of those allegations we've looked at,

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 1   there was an explanation of what was actually done in the

 2   investigation.

 3   Correct?

 4   A.   I did not write the report, so I don't know.

 5   Q.   I'm asking you: What we read earlier today, every one of

 6   those allegations that we looked through, there's an

 7   explanation of what the company did to look into the

 8   allegations, isn't there?

 9   A.   I did not read each of them, so I can't say that for

10   sure, yes or no.

11   Q.   The ones we looked at, Ms. Kaucher.

12   A.   I'd honestly have to go back and read them. I did not

13   pay attention that specifically to look at that.

14   Q.   The jury has seen it, so I'm going to move on.

15   MR. WIRMANI: Can we bring up Plaintiffs' Exhibit

16   1851 just for the witness and counsel.

17   BY MR. WIRMANI:

18   Q.   Now, ma'am, you see on the screen in front of you this is

19   a letter from Ms. Joanne Cesario.

20   Correct?

21   A.   I do see that.

22   Q.   It's directed to Chris Thompson, the director of

23   compliance investigations.

24   Do you see that?

25   A.   I do.

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 1              MR. WIRMANI:  Can we blow that back down.

 2         Can we go to page 3 of that document.

 3    BY MR. WIRMANI:

 4    Q.   You can see here -- so Ms. Cesario sent detailed

 5    allegations to Janssen about off-label marketing and other

 6    allegations.

 7         Correct?

 8    A.   I don't know.  I'm not aware of what she sent him.

 9    Q.   This is not a document you've ever seen?

10    A.   I don't think so, no.

11    Q.   So you conducted -- you claim you personally conducted an

12    investigation into Ms. Cesario's allegations, but no one

13    actually shared the allegations with you?

14    A.   There were multiple components for which -- I can't speak

15    to all of them, because they involve attorneys.

16    Q.   These are the allegations that Ms. Cesario made, correct,

17    that we are looking at in that investigation report?  Clearly

18    they include allegations of off-label marketing, which is part

19    of what you said you investigated.

20         Correct?

21    A.   I have not read this document.  I do not know what she

22    sent Chris.  I would have to read it.

23    Q.   Were you ever provided documentation from Ms. Cesario

24    about what her allegations were?

25    A.   I would assume at that time I was.  I can't tell you
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 1 exactly what I was provided. It was a very long time ago.

 2 Q. Do you have a recollection of receiving documentation?

 3 A. I have a recollection that I was provided information.

 4 Otherwise, I would not have been able to investigate what I

 5 did.

 6 Q. Did you -- did you interview Ms. Cesario as part of your

 7 investigation?

 8 A. I specifically did not, but I believe others did.

 9 Q. So you remember not interviewing Ms. Cesario?

10 A. Correct.

11 Q. If you look at -- why don't we go to the top of that

12 document and just kind of flip through so the jury can see it.

13   MR. WIRMANI: Let's go to page 2, please.

14   At this time I'd offer 1851, Your Honor.

15   MS. BROWN: No objection.

16   THE COURT: So admitted.

17   (Plaintiffs' Exhibit 1851 in evidence.)

18   MR. WIRMANI: And could we publish that to the jury,

19 Ms. Johnson.

20 BY MR. WIRMANI:

21 Q. This is what we were referring to earlier, the letter

22 from Ms. Cesario to Mr. Chris Thompson.

23   Correct?

24 A. Correct.

25   MR. WIRMANI: Let's go to page 2 of that document.

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 1   BY MR. WIRMANI:

 2   Q.   You can see that letter is addressed to Ms. Morganelli,

 3   who you said early you don't know, and Mr. Grimes, who you

 4   said directed you to do the investigation.

 5         Correct?

 6   A.   Correct.

 7   Q.   The date there is 9/1 of '10.

 8         Do you see that?

 9   A.   I do.

10   Q.   The subject is "health care compliance violations."  The

11   first one there deals with Frank Murphy, district manager.

12         Correct?

13   A.   I do see that.

14         MR. WIRMANI:  Flip to page 2.

15   BY MR. WIRMANI:

16   Q.   There's an allegation about Nancy Peterson.

17         Correct?

18   A.   I do see her name at the top, yes.

19   Q.   Further allegations about both Mr. Murphy and Nancy

20   Peterson related to district sales meetings.

21         Do you see that?

22   A.   I do see that.

23   Q.   And that's actually -- I'll give you a chance to review

24   it if you want.  That's actually the allegation that we were

25   talking about that was substantiated, correct, the one dealing
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1   with unapproved sales aids?

2   A.   Do you want me to read it?

3   Q.   Yeah. You can take a second to read it.

4   A.   Okay.

5   Q.   So you see there that Ms. Peterson, right -- and we're

6   going to get to the comp plans, but I want to take a look at

7   this first. Ms. Peterson says that, on June 24th in the

8   morning, both Frank Murphy and Jeff Sowers had instructed the

9   KAMs Nancy Peterson, Brad Rothenberger and Bob Mumford to

10   discuss and review the SWITCHMRK abstract.

11   Do you see that?

12   A.   I do.

13   Q.   Nancy Peterson took the lead on this presentation.

14   Do you see that?

15   A.   I do.

16   Q.   Copies of this abstract had been made for each individual

17   in attendance.

18   Do you see that?

19   A.   I do.

20   Q.   So every one of the salespeople got a copy of this from

21   the KAMs at the direction of Mr. Murphy and Mr. Sowers.

22   Correct?

23   A.   That's what it says.

24   Q.   It says, "The abstracts were handed out and allowed to be

25   kept by the sales force."

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1   Do you see that?

2   A.   I do.

3   Q.   So they weren't taken back. Right? They were handed out

4   to the sales force, and the sales force took them with them,

5   took them home, out in the field.

6   A.   I see that.

7   Q.   It says, "The abstract was not marked or in any way

8   indicated for training purposes only."

9   Do you see that?

10   A.   I do see that.

11   Q.   In the context of this abstract, do you agree with me now

12   that, when we're talking about abstracts, we are talking about

13   off-label information?

14   A.   I am not sure what the SWITCHMRK abstract is.

15   Q.   That's not what I'm asking, Ms. Kaucher.

16   When we were talking about an abstract, which usually

17   precedes a study, would you agree with me that an abstract is

18   not going to be on the label of a particular drug?

19   A.   I wouldn't say a hundred percent.

20   Q.   Are you aware of abstracts being on the label of any

21   drugs?

22   A.   I can't specifically, but I know that abstracts may be

23   based on publications, which can be in labels, if I

24   understand.

25   Q.   Ma'am, you're the -- you were the health care compliance

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 1   officer over the entire Janssen operations, correct, from 2010

 2   to 2014?

 3   A.   Entire Janssen operations, no.

 4   Q.   The entire Janssen Prezista, Intelence operations,

 5   correct?

 6   A.   Prezista, Intelence specifically, yes.

 7   Q.   Okay.

 8        And part of your job was to ensure that the sales force

 9   was compliant with the company's policies and procedures.

10        Correct?

11   A.   Correct.

12   Q.   One of those policies and procedures was that they were

13   not supposed to have inordinate amounts of off-label

14   information given to them.

15        Correct?

16   A.   They're not supposed to have inordinate amounts of

17   off-label?  I don't think our policies specifically state

18   that.

19   Q.   The policies state that the distribution of the

20   information that is off-label that is given to salespeople is

21   supposed to be for information purposes only.

22        Correct?

23   A.   Repeat the statement.  I'm sorry.

24   Q.   The policies say that any off-label information that is

25   provided to sales force -- the sales force is supposed to be
```

1   for educational purposes only.

2   Correct?

3   A.   That's correct.

4   Q.   Okay.

5   And the policies say that the sales force is only

6   supposed to be given the off-label information they need for

7   their educational purposes.

8   Are you aware of that?

9   A.   That they're only supposed to be given what they need for

10 their educational purposes?

11 Q.   Right.

12   That they're not supposed to be given too much of it;

13 that they only need enough to be educated.

14 A.   I don't recall that our policies specifically said that.

15 Q.   Okay. We'll come back to it and take a look.

16   But as the -- as the compliance officer for these two

17 drugs, when you see allegations that abstracts are being

18 handed out to the sales force without disclaimers, that each

19 salesperson is getting a copy, are you telling the jury you

20 don't suspect that that's off-label information?

21 A.   I don't suspect that it's off-label information. It may

22 be.

23 Q.   As a compliance officer, you would have concerns if

24 abstracts were being handed out to the sales force without a

25 disclaimer that they shouldn't be used in the field?

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1 A.   I would want a disclaimer on it so it was clear.

2 Q.   And the reason it would need a disclaimer and the reason

3 you'd be concerned is because abstracts are off-label

4 information.

5 A.   Some of them may be. That is correct.

6 Q.   And as a compliance person, you wouldn't just assume that

7 the abstract wasn't off-label; you would go investigate, and

8 that would be something you take seriously.

9   Correct?

10 A.   Repeat the last statement. I'm sorry. I wasn't

11 tracking.

12 Q.   If you -- if you heard allegations that abstracts were

13 being distributed to the sales force, you would not just

14 assume this must be some on-label abstract, would you?

15 A.   I would want to understand what they were; that's

16 correct.

17 Q.   You would go look to make sure that off-label information

18 isn't being distributed to the sales force, wouldn't you?

19 A.   That's correct.

20   THE WITNESS: Could I please ask that the blinds be

21 turned down a little bit. It's just shooting in my eyes a

22 little bit.

23   THE COURT: The blinds in the back?

24   THE WITNESS: Yes. If you don't mind. I'm sorry.

25 Just a little bit.

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 1              THE COURT:  Kim.

 2              THE WITNESS:  I'm sorry.

 3              THE COURT:  Ms. Brown, don't do it.  I've got Kim.

 4   She's in charge of the blinds.

 5              THE DEPUTY COURT CLERK:  All the way back?

 6              THE WITNESS:  Yeah, just a little bit or turn them

 7   up.  It's just in my eye a little bit.  I'm sorry.

 8              THE COURT:  I can only be responsible for one person.

 9   I don't want responsibility for everybody else in the

10   courtroom.  So if something goes wrong with Kim, I'll take it.

11   I'll take the hit.

12              THE WITNESS:  Thank you.  I appreciate it.

13   BY MR. WIRMANI:

14   Q.   Ma'am, and then it says that following this distribution

15   of these abstracts, there was an active discussion about how

16   to combat and compete with Merck's new drug, Isentress.

17          Do you see that?

18   A.   I do see that, yes.

19   Q.   It goes on to discuss another abstract that was handed

20   out, that Frank Murphy had Bryan O'Dea -- you remember you set

21   up the interview with Mr. O'Dea.

22          Correct?  We saw that email?

23   A.   I do.

24   Q.   Okay.

25          Frank Murphy had Brian O'Dea distribute copies of
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1 another abstract, "The Merit Reprint."

2   Do you see that?

3 A.   I do.

4 Q.   Okay.

5   Do you still think that's on-label information?

6 A.   I don't recall what the Merit Reprint is.

7 Q.   You conduct -- you said you conducted the investigation,

8 and you're telling this jury you don't remember what material

9 was at issue?

10 A.   From 13 years ago, no, I do not recall.

11 Q.   You did tell the jury last week that the investigation

12 involved off-label information.

13   Correct?

14 A.   Her allegation, I believe, was, yes.

15 Q.   Okay.

16   And that is consistent with the concerns we see here

17 about abstracts being handed to the sales force without a

18 disclaimer?

19 A.   But abstracts handed to the sales force doesn't mean they

20 were promoting off-label to customers.

21 Q.   That's not my question, ma'am.

22   I'm asking: Allegations that off-label information was

23 being distributed and used in the field, that is consistent,

24 right, the first part of that is consistent with what we see

25 here. Off-label information being distributed to all

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1 salespeople with no disclaimer and no direction that it not be

2 used in the field.

3 A.   That appeared similar to the other document you showed

4 me, yes.

5 Q.   And what -- what she alleges is that right after this was

6 handed out, there was an active discussion about how to

7 compete with a competitor drug of Merck.

8 A.   I do see that that was stated.

9 Q.   So, again, that would be something that would concern you

10 from a compliance perspective.

11   Correct?

12 A.   I would want to understand specifically what was

13 discussed, but I don't have those details here.

14 Q.   Handing out unapproved materials to all the salespeople,

15 no disclaimer, and then going into a conversation about how

16 we're going to compete with the drug of Merck, that would

17 concern you?

18 A.   I would want to understand the specific situation, which

19 I would have likely asked. I don't recall it specifically

20 now.

21 Q.   You just -- you don't remember?

22 A.   I don't remember these details, no.

23 Q.   Okay.

24   Last week you remembered the steps you took. You were

25 confident that you did it. You were confident in your

1   findings. This week when you see the documents you don't

2   remember?

3   A.   I recall generally that I was asked to investigate things

4   by Tim Grimes, and I recall letting him know that I did not

5   find anything.

6   Q.   And you'd agree with me that the ultimate findings of

7   this investigation report, they're inconsistent with your

8   testimony that the allegations were unsubstantiated.

9   A.   I don't think it's inconsistent. What I was asked to

10 look into was off-label promotion, and I did not find any

11 allegations. This is talking about distributing something

12 internally. It is different.

13 Q.   Well, let's read on.

14   So there's another abstract that's handed out. Again,

15 copies were made for everybody that's in attendance.

16   Correct?

17 A.   I do see that, yes.

18 Q.   Again, the sales reps were allowed to keep the abstracts.

19   Correct?

20 A.   Yes. I see that here.

21 Q.   It says, "Once again, these abstracts were not labeled in

22 any way for training purposes."

23   Correct?

24 A.   I do see that.

25 Q.   And then again, an active discussion was led on how to

1   compete with another competitor drug.

2   Right?

3   ViiV's new drug. It looks like Selzentry.

4   Do you see that?

5   A.   I do.

6   Q.   So, again, off-label -- what appears to be, to me, to be

7   off-label information is handed to the sales force. Copies

8   are made. No disclaimer is given, and then immediately, a

9   discussion is held about how to compete with a competitor

10 drug.

11 A.   Are you asking me a question?

12 Q.   Is that not what this appears to be to you?

13 A.   That is what it says. It doesn't say that was done with

14 customers.

15 Q.   Ma'am, it doesn't say it was done with customers. What

16 Ms. Cesario is alleging is we were handed a bunch of

17 unapproved materials and then, immediately thereafter, we had

18 a discussion about how we were going to compete with a

19 competitor drug.

20   Correct?

21 A.   I see that it says that, yes.

22 Q.   The implication of that is pretty darn clear, isn't it?

23 A.   No, it is not.

24 Q.   Again, "Neither abstract reprint had any type of

25 documentation to inform or disclose that this abstract could

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 1   not be used in the field with customers."

 2         You see that.

 3         Correct?

 4   A.   I see that.

 5   Q.   And these are the allegations that match up with the

 6   investigation report where there was substantiated findings

 7   that Frank Murphy and Nancy Peterson were distributing

 8   information, unapproved, that clearly appears to be off-label

 9   to the sales force.

10         Correct?

11   A.   Correct.

12   Q.   And then when we go to the allegations, we find that it's

13   actually more than just distributing it.  It's distributing it

14   and then immediately talking about how to go out and compete

15   with a competitor's drug.

16   A.   I have no specific information that those two were

17   related.  It does not say here that they were.

18   Q.   Ma'am, when -- are you saying that from a compliance

19   perspective when -- if you received this document and you saw

20   allegations that abstracts were handed to the sales force

21   without a disclaimer and then the employee said, And then

22   right afterwards we had an active discussion about how to

23   compete with a competitor drug, your response to that would be

24   I don't think this was used in the field?

25   A.   What I'm saying is I don't see it here, and I don't have
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 1  the specific notes from the investigation to verify what was

 2  asked.  So I'm not going to make any insinuations that that is

 3  what was then done.

 4  Q.   Well, is it your job to investigate compliance issues and

 5  make sure the company is compliant, or is it your job to

 6  protect the company?

 7  A.   I do investigations to verify that things were done

 8  appropriately against our policies, or not sometimes.

 9          MR. WIRMANI:  Take that back down a little bit,

10  Ms. Johnson.

11          And can we go to -- can we go to page 4 of that

12  document.

13  BY MR. WIRMANI:

14  Q.   You see there, in the second paragraph in that document,

15  Ms. Cesario alleges that "Discussed on this day was how we are

16  being reimbursed with sales compensation.

17          Do you see that?

18  A.   I apologize.  Can you explain what the document is I'm

19  looking at?  I'm just not sure.

20  Q.   This is a -- this continues to be Ms. Cesario's

21  allegations, right, that were brought to the company, the same

22  allegations that my clients allege that she made years ago.

23          Okay?

24  A.   The letter that she sent to Chris Thompson.

25  Q.   Correct.
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1   A.   Okay. Thank you for clarifying.

2   Q.   You're welcome.

3   And we looked earlier, correct, we looked at that

4   portion of the investigation report. I believe it was

5   Allegation Number 6 that talked about her allegations about

6   the compensation plan.

7   Do you recall that?

8   A.   I do recall that.

9   Q.   Okay.

10   And what the report ultimately concluded was there were

11   some allegations, but they weren't spelled out in the

12   investigation report.

13   You agree with that?

14   A.   Some of the allegations were not spelled out?

15   Q.   The allegations about the investigation -- or about the

16   compensation plan, they were not spelled out in the

17   investigation report.

18   Correct?

19   A.   I'm not -- I'm not understanding what you mean.

20   Q.   When we look at --

21   A.   The allegations were stated in there.

22   Q.   The allegation that was stated was that there were was

23   some issue that -- that Ms. Cesario was complaining about with

24   respect to the compensation plan.

25   Do you recall that?

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1 A.   I do.

2 Q.   There was no detail about what in particular she was

3 saying was wrong with it?

4 A.   Correct.

5 Q.   There was nothing in the investigation report about the

6 compensation plan encouraging off-label sales, was there?

7 A.   I did not see that that was stated, no.

8 Q.   And the response from the company was that her complaints

9 were irrelevant because business leaders and others were the

10 ones who put together the compensation plan.

11   Correct?

12 A.   I do recall that, yes.

13 Q.   So let's look at what Ms. Cesario actually alleged. She

14 says that -- with respect to the sales compensation plan, she

15 goes on to say that At this meeting we learn in greater detail

16 how our Intelence numbers compete with the drug Selzentry.

17   Do you see that?

18 A.   I do.

19 Q.   And she says that Intelence only has a

20 treatment-experienced indication, whereas Selzentry has a full

21 label.

22   Correct?

23 A.   I do see that.

24 Q.   "Full label" means that it can be legally marketed to

25 both treatment-experienced and treatment-naive patients.

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1   Correct?

2   A.   I believe so.

3   Q.   The next sentence says, "Selzentry is indicated for both

4   naive and treatment-experienced HIV patients."

5   Correct?

6   A.   I see that.

7   Q.   So the situation is these Janssen employees, including

8   Ms. Cesario, are selling the drug Intelence, and they can only

9   legally market for treatment-experienced patients.

10   Correct?

11   A.   Correct.

12   Q.   They are competing against a drug that has a full label

13   and can be sold to both treatment-naive and

14   treatment-experienced patients. That's what that document

15   says.

16   Correct?

17   A.   It does, yes.

18   Q.   And she goes on to allege that "At this meeting we

19   learned that, if a provider writes a script for Selzentry in a

20   naive setting, the sales force gets directly hit in a negative

21   way."

22   Do you see that?

23   A.   I do see that.

24   Q.   So she's basically saying that, if a doctor that I'm

25   responsible for writes a prescription of Selzentry for a naive

 1 patient, I take a hit as a Janssen salesperson on my

 2 compensation.

 3   Do you see that?

 4 A.   I see that's what it states.

 5 Q.   And she says, "Therefore, in essence, sales compensation

 6 has it set up so that Intelence indirectly competes with

 7 Selzentry's full label."

 8   Do you see that?

 9 A.   I do see that.

10 Q.   So she says the same exact thing is happening with

11 Merck's drug Isentress.

12   Do you see that?

13 A.   I see that.

14 Q.   Those are the same competitor drugs that we were looking

15 at earlier in the context of these unapproved abstracts being

16 handed out to the sales force.

17   Correct?

18 A.   I see that.

19 Q.   It says that Isentress has a full label and has a naive

20 indication.

21   Do you see that?

22 A.   I do.

23 Q.   She says that, "Under the portfolio bucket of our sales

24 compensation, it is as though our sales reimbursement is set

25 up for Intelence to compete once again with Isentress's naive

1 scripts."

2   Do you see that?

3 A. I do.

4 Q. What Ms. Cesario is alleging is that the way the sales

5 force compensation is set up is effectively encouraging them

6 to sell Intelence to their doctors for naive patients.

7 A. It appears she's stating that.

8 Q. And you're well aware of the fact that Intelence never

9 had a naive indication.

10   Correct?

11 A. Not that I know of.

12 Q. So marketing and encouraging a salesperson to market

13 Intelence for naive patients, that would be off-label

14 marketing?

15 A. If marketing encouraged sales to promote for naive?

16 Q. Yes. That would be off-label marketing?

17 A. It could be considered off-label, yes.

18 Q. It would be off-label marketing?

19 A. Yes.

20 Q. Not considered.

21   Correct?

22 A. Yes.

23 Q. And what Ms. Cesario is saying is, you've done that

24 indirectly by creating a compensation plan that penalizes me

25 for not selling Intelence and not marketing the product to

  1 naive patients.

  2   That's what she's alleging, isn't it?

  3 A.   It appears that's what she's alleging.

  4 Q.   And none of those allegations actually appear in the

  5 investigation report that we looked at earlier, do they?

  6 A.   The one that you showed me, I did not see that there.

  7 Q.   Right.

  8   What you saw is that Joanne Cesario had raised

  9 allegations about the comp plan, Frank Murphy basically said,

 10 Stop complaining, and the investigation said, Well, this is

 11 just irrelevant because we have more important people higher

 12 up in the company who are creating the comp plan?

 13 A.   What I also read is that the statement was it was unfair,

 14 but it did not explain in that investigation what that meant,

 15 so I don't know how this was reconciled.

 16 Q.   Exactly.

 17   You don't know how they were reconciled because that's

 18 not Ms. Cesario claiming that this is unfair. That's

 19 Ms. Cesario complaining that, The way you have set up my comp

 20 is encouraging me to market this product illegally, isn't it?

 21 A.   I see that's what she's saying here.

 22 Q.   And you understand that there has been testimony and

 23 allegations in this case by my clients that the comp system at

 24 Janssen was set up to encourage off-label marketing.

 25   Are you aware of that?

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1   A.   I am not aware of that specific allegation.

2   Q.   And my clients have alleged that, whatever investigation

3   Janssen did into Joanne Cesario's allegations, it was

4   perfunctory. It wasn't sufficient.

5   Are you aware of that?

6   A.   I'm aware of it because you had told me previously.

7   Q.   And what we have now seen is that Ms. Cesario raised very

8   detailed allegations about a compensation system that was

9   encouraging illegal off-label marketing.

10   Correct?

11 A.   Where does it say "encouraging off-label marketing"? I'm

12 sorry.

13 Q.   Ma'am, I'm not saying it says it.

14 A.   Oh.

15 Q.   That's clearly what she is implicating with what she is

16 stating in that allegation, isn't it?

17 A.   I am not going to speak to what she's implicating. I'm

18 reading what it says on the paper.

19 Q.   And the company's response is not to re-examine its comp

20 plan.

21   Correct?

22 A.   The company's response is what? I'm sorry.

23 Q.   The company's response to these allegations that we

24 looked at in the investigation report, the company's response

25 is not to re-examine its comp plan.

1   Correct?

2 A.   Correct.

3 Q.   Instead, the investigation report doesn't detail, right,

4 it doesn't detail what the allegations are. It basically says

5 that her allegations are irrelevant because the comp

6 committee, the business leaders, they're the ones who get to

7 set the comp plan?

8 A.   I can't speak to whether this is the same exact thing

9 that was stated in that report because, as I read that, it

10 says "unfair" but it doesn't explain. So I can't state that

11 they're the exact same thing or how this specifically was

12 reconciled because it was not addressed to me.

13 Q.   You understand that Ms. Cesario raises six allegations in

14 this letter and that that investigation report details six

15 allegations.

16   Are you aware of that?

17 A.   From what you showed me, yes.

18 Q.   Okay.

19   And it's now your testimony that you don't think that

20 what the investigation report was referring to about the comp

21 plan is the same thing as what Ms. Cesario is saying here in

22 her letter?

23 A.   What I'm saying is I don't know because I wasn't

24 addressed this one, and that one says "unfair" without an

25 explanation of what that means. So I don't want to insinuate

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 1  that they're the same thing or nothing -- nothing was done

 2  with this.  I don't know the answer to that.

 3  Q.   Are you aware of the fact that we've seen evidence in

 4  this case that over 70 percent of Intelence sales were

 5  off-label?

 6  A.   I'm not aware of that.

 7  Q.   Does that seem like a figure that might corroborate what

 8  Ms. Cesario is alleging here?

 9  A.   No.

10  Q.   Do you ever wonder why the off-label sales of Intelence

11  were so high?

12  A.   Spontaneous use can happen, that as a physician's choice,

13  how they prescribe.  That doesn't mean we are selling it

14  off-label.

15  Q.   So your -- your perspective from compliance is to assume

16  that, if you saw allegations like this and you knew that

17  70 percent of sales were off-label, you would assume that

18  they're spontaneous sales?

19  A.   I would because I do not think we were doing anything

20  off-label as a company, so, yes, I would assume that it is

21  spontaneous use.

22  Q.   And is that how you operated as the compliance officer

23  for Janssen between 2010 and 2014?

24  A.   Can you clarify what you mean by that?

25  Q.   You just gave --
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 1 A.   How we operated like what?

 2 Q.   You just gave us an answer about what you would assume,

 3 what you think happened. I'm asking you is that how you

 4 operated as the compliance officer for Janssen between 2010

 5 and 2014?

 6 A.   How I operated with Janssen was to do my job as a

 7 compliance officer.

 8   MR. WIRMANI: Can we push that down.

 9 BY MR. WIRMANI:

10 Q.   Would you agree with me at least, Ms. Kaucher, that --

11 that what we just went through, comparing the investigation

12 report to Ms. Cesario's allegations, that that is consistent

13 with what my clients allege happened to Ms. Cesario, which is

14 that a perfunctory, insufficient investigation was run

15 regarding her allegations?

16 A.   No, I do not.

17   MR. WIRMANI: Can we bring up Exhibit 1854 one more

18 time.

19   Can we go to page 3, allegation number 2.

20 BY MR. WIRMANI:

21 Q.   You see here that another allegation that Cesario made,

22 that was Frank Murphy has engaged in off-label discussions

23 with several physicians while on sales calls with Cesario.

24   Do you see that?

25 A.   I do.

1 Q. Are you aware of the fact that my clients, a number of

2 other salespeople that have testified in this case, have

3 claimed the same thing, that they would go on sales calls with

4 their managers, including folks like Nancy Bartnett and Frank

5 Murphy, and that these managers would market to doctors

6 off-label.

7   Are you aware of that?

8 A. I'm not.

9 Q. And again, you see the conclusion that this allegation is

10 unsubstantiated.

11   Do you see that?

12 A. I do see that.

13 Q. And then it describes what the investigation was.

14   Correct?

15 A. I do see that.

16 Q. It says, "Grimes spoke with several of the physicians to

17 whom Murphy allegedly spoke off-label."

18   Do you see that?

19 A. I do.

20 Q. All of the physicians denied that Murphy participated in

21 off-label discussions with them.

22   Do you see that?

23 A. I do.

24 Q. It says, "Further, all the sales reps interviewed, except

25 Cesario, stated that they had never heard Murphy engage in any

 1 off-label discussions with health care providers."

 2   Do you see that?

 3 A.   I do.

 4   MR. WIRMANI: Can we blow that back down.

 5 BY MR. WIRMANI:

 6 Q.   And at least according to this document, that was the

 7 extent of the investigation.

 8   Correct?

 9 A.   I -- I don't know. I can just read that that's what the

10 allegation said and that's what the finding says.

11 Q.   So if you read on the document that that's what the

12 allegation is and that's what the finding is, then when I

13 asked you, based on this document that was the extent of the

14 investigation, wouldn't your answer be yes?

15 A.   I don't know if it was the extent of the investigation.

16   THE COURT: Based on the document, ma'am. Listen to

17 the question. Listen to the question that's being posed to

18 you.

19   THE WITNESS: I'm not understanding the question. I

20 apologize.

21 BY MR. WIRMANI:

22 Q.   Based on the document that we just read together, right,

23 based on that document, does that document show that the

24 extent of the investigation was going and asking doctors if

25 this was true and then going and asking other sales reps?

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 1  A.   That appears that's all that's here, yeah.

 2  Q.   Okay.

 3       And I told you earlier and asked you if you were aware

 4  of the fact that Ms. Penelow testified that when these issues

 5  occurred with Ms. Cesario, that the sales force banded

 6  together to protect and save Frank Murphy.

 7       Do you recall that?

 8  A.   I'm aware that you told me that, yes.

 9  Q.   Okay.

10       And when you were describing your investigation -- do

11  you think that this is now your investigation, or are you

12  still thinking you did a different investigation?

13  A.   I'm sorry.  Can you repeat the question?

14  Q.   Do you think now this is your investigation, or do you

15  still think you did some other investigation?

16  A.   I recall doing these actions.  I may have done them with

17  Tim Grimes.  I don't recall.  But I do recall interviewing

18  physicians.  So what is here looks familiar.

19  Q.   Okay.

20       And, again, the documentation that we were provided

21  with respect to those underlying interviews, are you aware of

22  the fact that your name does not appear on any of the

23  interview reports?

24  A.   I am not aware that they did.  Again, I was instructed by

25  Tim Grimes, so I -- he may have had more information than I
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1 did.

2 Q.   Well, when you did your investigation, the one you

3 testified about last week, you said you did a lot more than

4 just talk to salespeople.

5   Right?

6 A.   Correct.

7   MR. WIRMANI: You can leave that up, Ms. Johnson.

8 BY MR. WIRMANI:

9 Q.   You said that you pulled data.

10   Correct?

11 A.   I did.

12 Q.   Did you pull data to see if these particular doctors, if

13 their off-label sales increased after Ms. Cesario alleged

14 Mr. Murphy talked to them off-label?

15 A.   I don't recall exactly what files I pulled at that time.

16 Q.   Okay.

17   And you would agree with me that nothing like that

18 appears in this final investigation report as an investigative

19 step that was taken?

20 A.   I see that it does not say that.

21 Q.   Nothing in this document discusses that these allegations

22 in particular were even discussed with Frank Murphy.

23   Correct?

24 A.   Correct.

25 Q.   And we saw earlier that when Mr. Murphy was asked, he

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1 actually admitted to handing out the abstract, didn't he?

2 A.   That Murphy admitted what?

3 Q.   To handing out the abstracts?

4 A.   Handing out abstracts, correct.

5 Q.   Correct.

6   But there's no reference in this allegation to

7 Mr. Murphy even being interviewed about this.

8   Correct?

9 A.   I -- I don't know.

10 Q.   Well, you could read the document.

11   Is there a reference in allegation number 2 to

12 Mr. Murphy being interviewed about Ms. Cesario's allegations?

13 A.   It doesn't specifically state it.

14 Q.   There's no mention of compliance, going on ride-alongs

15 with Mr. Murphy to see if Ms. Cesario's allegation can be

16 substantiated.

17   Correct?

18 A.   It doesn't outline those details.

19 Q.   Did you know that all of the people interviewed, all of

20 the sales reps, they were all interviewed on the same day?

21 A.   I'm not aware of the timing.

22 Q.   So the extent of this investigation was basically going

23 to the other side and taking their word over Ms. Cesario's.

24   Correct?

25 A.   No, because they also interviewed the physicians.

 1 Q.   And the -- Ms. Cesario is alleging that Frank Murphy is

 2 having off-label discussions with the physicians, right, and

 3 they go talk to the physicians, the physicians say, No, that

 4 didn't happen. Ms. Cesario claims she was there, and they

 5 take the word of the physicians over Ms. Cesario.

 6   Correct?

 7 A.   It appears so.

 8   MR. WIRMANI: We can put that back down.

 9 BY MR. WIRMANI:

10 Q.   Now, you mentioned, ma'am, that you did some of these

11 doctor interviews.

12   Correct?

13 A.   I recall that I had, yes.

14 Q.   Okay.

15   Which doctors did you speak to?

16 A.   I -- I couldn't tell you. I don't recall.

17 Q.   Where are your notes from those interviews?

18 A.   I don't know.

19 Q.   Where are the emails that you sent to Mr. Grimes

20 reporting the findings of your investigation?

21 A.   There's information. I can't share because it was

22 provided to attorneys.

23 Q.   You can share information -- you can share what you did,

24 ma'am.

25 A.   He was in their presence. I would need advice whether I

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 1  can share that or not.

 2  Q.   Okay.  We're not going to get into that.

 3       But where are the notes?  The notes -- you understand

 4  if you wrote up interview notes, those would not be

 5  privileged.

 6       You understand that.

 7       Correct?

 8  A.   I don't recall if I did or did not write the notes.  It

 9  was a long time ago, so I don't specifically recall if I wrote

10  the notes or not.

11  Q.   But you do recall the general practice in compliance

12  would be to document an investigation?

13  A.   Yes, I understand that.

14  Q.   And if you had done an investigation and reported it to

15  Mr. Grimes, you'd expect that Mr. Grimes would expect to see

16  some documentation coming his way.

17       Correct?

18  A.   I would have provided him the information from my

19  investigation of what I found, yes.

20  Q.   Right.

21       And that would have included documentation of what you

22  did and what you found out?

23  A.   I can't recall if I provided that to him verbally or in

24  writing.

25  Q.   Okay.
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 1          And because you can't recall that, there's no way for

 2    us to verify -- because we don't have those documentations --

 3    what you did and what you found.

 4          Correct?

 5    A.   I guess so.

 6    Q.   Okay.

 7          We just have to take your word that you did these

 8    things, that you found the allegations unsubstantiated, even

 9    though we have an investigation report that looks into the

10    exact same allegations during the exact same time period and

11    sustains multiple allegations.

12          Correct?

13    A.   What I recall is what I investigated, and it was not

14    sustained.

15    Q.   Was it that particular allegation that was not sustained?

16    A.   That looks very familiar to what I had looked into, yes.

17    Q.   Okay.

18          So are you telling us that's your investigation?

19    A.   It looks very familiar, yes.

20    Q.   Would it surprise you to know that the interview notes

21    from the doctors don't contain your name?

22    A.   He was my boss's boss.  So he may have been privy to

23    things that I was not privy to or had reviewed the report that

24    I was not privy to.

25    Q.   I'm talking about the notes that were taken from the
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 1   interviews with the doctors.  Those documents don't contain

 2   your name.

 3   A.   I haven't seen them also.  I don't know if they do or

 4   don't.

 5   Q.   So, Ms. Cesario, (sic) just so we're all -- or excuse me,

 6   Ms. Kaucher, just so we're all clear, last week you told the

 7   jury on -- it was prompting that -- those are the line of

 8   questions that came from Janssen's counsel.

 9        Correct?

10   A.   Yes.

11   Q.   I didn't ask you about Ms. Cesario when you were

12   testifying, did I?

13   A.   I don't recall if you did or not.

14   Q.   Okay.

15        Janssen raised Ms. Cesario in the context, do you

16   recall, of what Ms. Brancaccio and Ms. Penelow testified to.

17        Do you remember that?

18   A.   I think so, yeah.

19   Q.   And then she specifically came to you, right, to ask

20   about those allegations.  Because my clients are saying that

21   Ms. Cesario raised the same allegations, subsequently she was

22   terminated.

23        You're aware of that.

24        Correct?

25   A.   I -- I don't think that they're the same exact
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1 allegations.

2 Q.   You're aware that my clients allege that Ms. Cesario

3 raised allegations about off-label marketing and specifically

4 about studies, studies that Frank Murphy was distributing to

5 the sales force.

6   Are you aware of the fact those allegations appeared in

7 the complaint in this case?

8 A.   Yes. I'm aware of those allegations.

9 Q.   And last week, when Janssen's counsel brought up this

10 subject, they went into detail about the investigation that

11 you said that you conducted into Ms. Cesario's allegations.

12   Correct?

13 A.   Yes.

14 Q.   Okay.

15   You told the jury that you did the interviews, that you

16 pulled data, that you are the ultimate one who made the

17 findings, and your conclusions were that you could not

18 substantiate any of those allegations.

19   That's what you told this jury last week.

20   Correct?

21 A.   Yes. And I still stand by that, yes.

22 Q.   And now we have the documents. The only documents that

23 apparently exist, because otherwise they would be obligated to

24 provide them, about your investigation, and we know that

25 multiple of Ms. Cesario's allegations were substantiated.

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 1        Correct?

 2   A.    It appears through this report there were multiple -- I

 3   believe multiple.  I'd have to look, but it appears so, yes.

 4   Q.    And we know that other allegations of off-label

 5   marketing, particularly with respect to the comp plan, don't

 6   even appear to have been investigated by the company.

 7        Correct?

 8   A.    No, I would not agree with that.

 9   Q.    You would not agree that when we looked at earlier where

10   they said this is an irrelevant complaint about the comp plan

11   because it was created by the business leaders and the comp --

12   you don't think that that's an inadequate investigation?

13   A.    No.  I don't think that means it's inadequate.  I don't

14   know specifically what they did to look into it.  So, no, I

15   can't judge that it is or isn't.

16   Q.    But you are aware that my clients allege that the

17   investigation into Ms. Cesario's allegations was inadequate.

18        Correct?

19   A.    That what?  I'm sorry.

20   Q.    You are aware of the fact that my clients have alleged

21   for years that the investigation into Ms. Cesario's

22   allegations was inadequate?

23   A.    From what you have told me today, I have learned that

24   that is an allegation.

25   Q.    And we know that particularly Mr. Murphy had allegations
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1   brought against him that were substantiated.

2   Correct?

3   We now know that.

4   A.   Particular ones, yes.

5   Q.   Okay.

6   And we know that he basically got a verbal warning and

7   what appeared to be a letter from -- from upper management.

8   Is that fair?

9   A.   It appears it is from HR.

10 Q.   He received a three-month performance improvement plan.

11   Are you aware of that?

12 A.   I am not.

13 Q.   You have no recollection of Nancy Peterson being

14 terminated or suspended without pay, but we now know that she

15 also was engaged in conduct that Ms. Cesario had alleged that

16 the health care compliance investigation found was

17 substantiated, found that it actually occurred.

18   Correct?

19 A.   I do not recall what her disciplinary action was.

20 Q.   So instead of Ms. Cesario raising allegations about

21 off-label marketing that were unsubstantiated, we now know

22 that she raised allegations about off-label marketing and

23 other issues which were substantiated.

24   Correct?

25 A.   The off-label marketing was not substantiated.

1   Q.   The handing out of the abstracts and then discussing, how

2   we're going to go compete with competitor drugs, you can

3   characterize it how you want, those allegations were

4   substantiated.

5   A.   The internal distribution of the abstracts was

6   substantiated.

7   Q.   And we know that after -- some point after these

8   allegations were raised, Ms. Cesario was terminated.

9   Correct?

10   A.   I am not aware of the timing or the status of her

11   termination. I was not involved in that.

12   MR. WIRMANI: No further questions, Your Honor.

13   THE COURT: All right, thank you, Counsel.

14   MS. BROWN: Your Honor, may I approach for a moment.

15   THE COURT: You may.

16   MS. BROWN: Thank you.

17   THE WITNESS: Do I stay?

18   THE COURT: Yes, for now, because I don't know...

19   (Sidebar begins at 2:35 p.m.)

20   THE COURT: Folks, we're going to take at least a

21   15-minute break for the jurors and for everybody else except

22   for the counsel at sidebar. So let's get the jurors excused,

23   not dismissed for the day. I got to be very careful what I

24   tell these folks. Friday they'll run out on me.

25   (Jury exits the courtroom.)

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 1              THE COURT:  Folks, everybody, have a seat.

 2         Ma'am, you're only temporarily stepping out.  I haven't

 3   permanently excused you from the trial.  You can step out of

 4   the witness box.  Okay?

 5              (Sidebar begins at 2:36 p.m.)

 6              MS. BROWN:  All right, Your Honor, for the record, I

 7   need to request the opportunity to conduct a short examination

 8   of Ms. Kaucher on these new documents that we did not have at

 9   the time that I did mine.  And there are particular documents

10   that I would like to --

11              THE COURT:  Before we even get into what you want to

12   do, this was a witness called by Relators' counsel?

13              MS. BROWN:  Correct.

14              THE COURT:  You guys cross-examined and then failed

15   to disclose all of these documents, which a negative inference

16   instruction was given, and now you want to have the last word

17   with this witness after they've gone through these documents?

18              MS. BROWN:  Yes, Your Honor, given the nature of the

19   fact that the documents were not available to put into

20   evidence --

21              THE COURT:  But they're admitted?

22              MS. BROWN:  There are documents that counsel was

23   provided that he did not use on his examination that I want to

24   proffer, I would have used, and separately seek admission of.

25              THE COURT:  No.
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1   MS. BROWN: Okay.

2   THE COURT: You have certain documents in evidence.

3   To the extent you want to go through documents that are in

4   evidence at closing -- they're admitted, Ms. Brown. So I

5   don't think that there's any unfair prejudice to Janssen here.

6   It was their witness. They get the last word with this

7   witness even though it's a hostile witness. Ms. Kaucher

8   couldn't testify to half of it anyway. All she was doing was

9   reading literally verbatim what Mr. Wirmani was putting before

10 her. If he asked her one question off of the written word,

11 she can't even respond to it. So I don't think there's any

12 unfair prejudice. And you have those documents in evidence.

13 So if there's something in there that you believe is useful to

14 Janssen, you can close on it. But you're not going to get an

15 opportunity after this discovery violation to get the last

16 word on documents that you think may or may not have been

17 useful to you. That doesn't seem proper at all.

18   MS. BROWN: I understand.

19   THE COURT: Because that's -- what's going to happen

20 is you're going to go and then I'm going to have to allow

21 Mr. Wirmani a separate last-minute questioning. I don't know

22 that that's fair. But let me hear from Mr. Wirmani.

23   MR. WIRMANI: I just want to say, Your Honor, if they

24 had produced these documents like they were supposed to, which

25 they found over a 24-hour period, years ago, then they would

1 have had the document to examine Ms. Kaucher with. It defeats

2 the purpose of the adverse inference instruction. It is

3 supposed to let the jury draw an inference, if they choose to

4 do so, that these documents weren't helpful.

5   THE COURT: But I will say, Ms. Brown, these

6 documents, at least the investigation report, I'm not so sure.

7   But just remind me, Mr. Wirmani. What did you admit in

8 evidence besides the investigation report? I think that's

9 what was -- and the letter of the allegation. You do have a

10 letter from Cesario with six allegations, which, although

11 confusing because Ms. Kaucher couldn't testify, I think,

12 properly to it, they match the six allegations in the report,

13 and they have to because you represented when you produced

14 these documents that this is the investigation report for the

15 investigation she's talking about. So you have that. If you

16 want to do something with that and make an argument based on

17 what that evidence is before the jury, you're permitted to do

18 that.

19   MS. BROWN: Yes, Your Honor. I understand. I need

20 to make a record here. I understand the Court's ruling. I

21 understand counsel's argument.

22   THE COURT: Let me hear the rest.

23   MS. BROWN: I need to protect the record. I'm just

24 trying to make my record.

25   What I seek to do at this point -- I understand the

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 1  Court is denying the opportunity to question her.  I

 2  understand the Court's ruling.  I would like to admit into

 3  evidence documents that were produced, subject to the Court's

 4  order, that are the basis of the adverse instruction that

 5  counsel did not use.  Those would be, Your Honor, Amit Patel's

 6  interview memorandum over the course of two days, although it

 7  was represented it was only one, D-9296.  It is a business

 8  record as well as it goes to Janssen's intent.  I would seek

 9  to admit D-9289, Your Honor --

10            THE COURT:  Sorry.  Can I see the documents.

11            MS. BROWN:  Yes.

12            THE COURT:  By the way, I want to be clear.  There's

13  a difference between being able to admit a document and

14  question Ms. Kaucher again.  I want to be clear that I made

15  that ruling, but this is a separate issue.

16            MS. BROWN:  It is, Your Honor.

17            THE COURT:  -- build your record, but let me look at

18  this.

19        Mr. Wirmani, do you know what document I'm looking at?

20         MR. WIRMANI:  Yeah.  I didn't misrepresent anything,

21  Judge.  There was interviews that were done of doctors, which

22  were done over time, and there were interviews that were

23  scheduled to all be done -- and that's the document you said

24  came from Ms. Kaucher's computer -- all on the same day.  That

25  is what I represented.
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 1              MS. BROWN:  Just for the record, to respond, the

 2   actual interview notes from Mr. Patel that includes an

 3   interview with Mr. Murphy, which was also the subject of

 4   questioning, documents two days.  It is a multipage interview

 5   notes that talked in detail about these very allegations and

 6   the number --

 7              THE COURT:  Let me just do one document at time.

 8   Ms. Brown, this is a document where Mr. Murphy was

 9   interviewed?

10              MS. BROWN:  Yes, as well as all the sales reps.

11              THE COURT:  As well as the sales reps.

12         Mr. Wirmani, let me hear from you.

13              MR. WIRMANI:  I'm opposed to that, Your Honor.  First

14   of all --

15              THE COURT:  Let me ask you this before you're opposed

16   to it.  You represented, based on your questioning and based

17   on the investigation report, that Mr. Murphy was never

18   interviewed.  Do you recall that?

19              MR. WIRMANI:  I did not represent that.  I said he

20   was interviewed in the context of one allegation.

21              THE COURT:  But not on the off-label.

22              MR. WIRMANI:  But there was no -- no.  All I said is

23   there was no mention of an interview with him in the context

24   of that allegation in that report.

25              THE COURT:  No, I know.  And the implication there is
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 1 | that he was not interviewed. Correct?

 2 | MR. WIRMANI: That they -- well, whatever they did,

 3 | it wasn't important enough to document in the investigation

 4 | report.

 5 | THE COURT: That's not what I took from your

 6 | questioning. Your questioning was he was identified in this

 7 | allegation, he was spoken to, he wasn't here, and the clear

 8 | implication from that examination based on that one document

 9 | was that he was not interviewed. That, I think, is a little

10 | bit unfair. So if you're telling me -- but now here's the

11 | question. Are you -- I'm going to let Mr. Wirmani respond --

12 | for now I'm only comfortable saying I think it's permissible

13 | not to question Ms. Kaucher but to admit a document that

14 | Mr. Murphy was interviewed and what that interview indicated

15 | because it's part of the record of this investigation. Are

16 | you saying, though, Judge, if you're going to put that in,

17 | then I want all the interview notes in?

18 | MR. WIRMANI: No, I would just say --

19 | MS. BROWN: I do.

20 | THE COURT: Well, I am asking Mr. Wirmani. This is

21 | more for Relators. I will tell you the reason -- I was

22 | considering not putting any of this in. But you put a

23 | representation there -- and I'm not saying you did. You

24 | didn't say, Judge, I can argue later that that's not what I

25 | intended, but what I think, at least based on my objective

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 1  viewing, is that it doesn't seem fair to me.  You have an

 2  advantage with having the document and the last word with

 3  Ms. Kaucher.  That, I've giving you.  But if Mr. Murphy was

 4  interviewed in that allegation, then I think that portion

 5  should be admitted, unless you're telling me, Judge, then it

 6  all should go in.

 7          MR. WIRMANI:  No, I would just say, Judge, first of

 8  all, just for the record, I wasn't trying to draw an

 9  implication that was inconsistent with what I knew the record

10  to be.

11          THE COURT:  By the way, and I would -- I was not

12  accusing you.

13          MR. WIRMANI:  I understand.

14      I would say that, if you're correct that he was --

15  Mr. Murphy was interviewed about that allegation, Allegation

16  Number 2, then I'd ask that it be put in there in redacted

17  format only with his interview with respect to Allegation

18  Number 2.

19          THE COURT:  So far we're on the same page with that.

20  Let me hear -- do you hear that part?

21          MS. BROWN:  I am.

22          THE COURT:  It's only with respect to the allegation

23  that I believe you may have given the impression to the jury

24  he was not interviewed.

25          Now, Ms. Brown, let me hear the rest of this.
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1   MS. BROWN: Okay. I am not on the same page with

2   that, Your Honor. I would seek admission of the entire

3   document, which is all of the interview notes, for a number of

4   reasons, Your Honor. This is one of the documents that is the

5   subject of an adverse inference that we are going to receive

6   and we are going to have to deal with the implications of, and

7   this is a document, for whatever strategic reason over the

8   last hour and a half, that counsel chose not to use, but,

9   Your Honor, it details in great detail what these interviews

10   were about. For example --

11   THE COURT: Let me do this. I can even take a look

12   at this on the break. For now, I'm going to take a longer

13   break anyway because I need some time. Let me just -- just go

14   through documents. All the documents that were produced or

15   just these?

16   MS. BROWN: Well, so it's this one, Your Honor, which

17   is the details of most of the interviews.

18   THE COURT: Okay.

19   MS. BROWN: There is a follow-up interview notes with

20   Nancy Peterson, D9298, that I would seek to admit. I would

21   seek to admit D-9297.

22   THE COURT: Which is what?

23   MS. BROWN: Which is an interview with the doctor

24   which is also the subject of this questioning.

25   THE COURT: Just wait, Mr. Wirmani.

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1	MS. BROWN: Then I would seek to admit D-9291, which
2	came from Ms. Kaucher's computer and identifies the number --
3	THE COURT: Now, can I hold on to these folders?
4	MS. BROWN: Of course.
5	THE COURT: So here is what I am going to tell you
6	because I don't ever do this on sidebar, and we can address
7	this at the end of the day. I'm telling you right now,
8	Mr. Wirmani, think about it because I will tell you I am going
9	to consider this, and here's why. I'm just putting this out
10	there, and I'm sure we have more to argue at 5 o'clock. But
11	I've given a significant, I think, instruction to the jury
12	that they are going to hear in the final instructions.
13	Now, I understand that you didn't necessarily have to
14	choose to go through all the documents that were produced and
15	you could be selective about that and that's fair. But I am
16	considering that these documents, for a full picture to the
17	jury -- because what I'm not preventing Janssen from doing --
18	because I know that Mr. Marketos or one of you, whoever's
19	closing, is going to raise this inference again, without a
20	doubt, in closing. Janssen has the right to argue, look --
21	they can argue that We withheld them but they're not harmful.
22	I understand that you could infer they're harmful to us.
23	We're telling you they're not, and here's why.
24	They're allowed to argue that.
25	Now, how can they make that argument in good faith if

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 1  we say only a piece of what they turned over, which was the

 2  catalyst to the instruction, is before the jury?  Now, by the

 3  way, I don't want an answer to this.  I'm telling you that

 4  that is what I'm going to ask you all to address because what

 5  I don't want to do is give a negative inference instruction,

 6  which I've given, and also handcuff -- who's doing the closing

 7  for you all?

 8            MS. BROWN:  Me.

 9            THE COURT:  I'm not going to handcuff her when she

10  can't even make the argument that the inference should not be

11  made, because the instruction doesn't say, for me, make the

12  inference.  It says you may, but you're not required to.  And

13  you're going to argue that that inference absolutely should be

14  made.

15       There's no way that's not coming out from the Relators

16  in some form or fashion.

17       Briefly, I'll hear you.

18         MR. WIRMANI:  Just briefly, Your Honor.

19       I would say if I made a representation that is

20  inconsistent with the documents, I agree you should have a

21  right to put in that redacted document.

22       I would -- secondly, I would say that if you actually

23  go through that investigation report, four of the allegations

24  are unsubstantiated.  Frank Murphy was punished.  There's a

25  lot for you to argue with in there --
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 1            MS. BROWN:  I know.

 2            MR. WIRMANI:  -- that an adequate investigation was

 3  done.

 4            THE COURT:  But let me ask you this, Mr. Wirmani.

 5  I'll even say to this -- and I'll say this now.

 6        If you're saying, Judge, if you're inclined to allow

 7  these remaining documents to go in, then I want to be the one

 8  to move it in.  I don't even want the optics of Janssen being

 9  able to admit them.  I will consider that, too.

10            MR. WIRMANI:  Okay.

11            THE COURT:  Because here's what I'm not going to do,

12  right.  We finished with the witness.  You promptly raised

13  this issue before I dismissed Ms. Kaucher, and I think that's

14  appropriate, to wait.  But I'm not going to necessarily give

15  an appearance by timing that Mr. Wirmani was trying to

16  preclude these documents from being admitted and now you get

17  to have them in.

18            MS. BROWN:  Sure.  And I think that's fair,

19  Your Honor.

20            THE COURT:  So that's the other thing I'm going to

21  allow you to consider, but it doesn't need to be addressed

22  now, because if I'm dismissing this witness, at the end of the

23  day or even Monday, these can be moved to be admitted,

24  correct?

25            MS. BROWN:  Sure.  Absolutely, Your Honor.  And I
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1   would be fine if they were moved outside the presence or by

2   Relators' counsel. I am not looking to make a show about

3   this.

4   THE COURT: I think they have to be moved in front of

5   the presence of the jury because, otherwise, they don't know.

6   MS. BROWN: Fine. Okay.

7   THE COURT: I don't know. I think they need to be

8   present when documents are admitted, even if he's not

9   displaying them.

10   MS. BROWN: Sure. Whatever --

11   MR. WIRMANI: And that's fine. And I'll defer.

12   Whatever the Court ultimately decides, my position is clear.

13   Can I raise one other issue that I'm a little concerned

14   about? I don't understand that witness's testimony. She

15   claimed that she conducted an investigation that was separate

16   and apart from what --

17   THE COURT: No, it's the same investigation. I think

18   she is -- I don't know whether this is -- her recollection is

19   off, but my understanding -- and you guys may be -- this is

20   going to be a tough one -- is that she did part of this

21   investigation, reported to Grimes, and -- but I've got to tell

22   you, if compliance folks are writing that they did interviews

23   when somebody else did them, I mean, they really need to clean

24   this up because I don't know any compliance department in the

25   universe where if you and I work together and I'm conducting

1   interviews they say Ms. Brown conducted the interview.

2   MS. BROWN: Right.

3   THE COURT: It would say, Mr. Quraishi conducted the

4   interview and reported to Ms. Brown.

5   But I don't know how to explain --

6   MR. WIRMANI: I thought she was going to say, "I was

7   at the interview." She didn't even say that. And she did not

8   remember -- she distanced herself from this investigation and

9   tried to create the appearance that she did some other

10   investigation. If there was one, I'd like the documents.

11   MS. BROWN: I mean, my --

12   THE COURT: My point is simply this: For now you

13   have the testimony as is, and Janssen has represented that

14   these documents are the documents that are -- pertain to her

15   investigation as she testified.

16   But I'm going to say this, Ms. Brown, in an abundance

17   of caution on the sidebar. I want you and Mr. Wyatt to go

18   back this weekend and make sure there are no separate

19   documents, because here's one thing that is a little bit

20   surprising to me.

21   MS. BROWN: Yeah.

22   THE COURT: Even if you believe that you can

23   compartmentalize her and say, "I only investigated this piece

24   for Mr. Grimes and reported it" -- she memorized interviews

25   with several doctors, several sales reps. Never wrote a thing

1   down on a piece of paper. Wait. Memorized it. Then went,

2   after all those interviews, to her boss's boss and

3   regurgitated the interview information? There is no interview

4   in the universe that is conducted by memory like this. If she

5   said, "I interviewed one person. I went to Grimes and I just

6   informally told him" --

7   MS. BROWN: Yeah.

8   THE COURT: But she testified she interviewed several

9   doctors and several sales reps. And I know -- I wish -- I was

10   wishing Mr. Wirmani -- I almost asked it myself, but I really

11   don't like to ask witnesses questions.

12   MS. BROWN: Yeah. Sure.

13   THE COURT: But it's her testimony that she memorized

14   all this? Because she needs to say, "No. I must have written

15   it down." And if that's the case, somebody needs to go back

16   this weekend and find it.

17   MS. BROWN: And let me just tell you -- and this is

18   hard for me because I obviously couldn't talk to her. Right?

19   I mean, all I knew is what I elicited.

20   What I think happened, Your Honor, and why these notes

21   are important to me, not -- I believe she was with Amit

22   Patel -- when she says my boss's boss, it's Amit and then Tim

23   Grimes. And Amit has very detailed notes of these

24   conversations.

25   What I know from working for the company is that these

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 1  investigations, you don't have one person --

 2          THE COURT:  You believe these are the notes and that

 3  she didn't write them but Dr. Patel did.

 4          MS. BROWN:  That is what I believe.  It squares with

 5  her testimony and the documents, and believe me, I could

 6  represent --

 7          THE COURT:  So why don't we do this.  Before I

 8  address these documents and whether they're admissible, why

 9  don't you confirm that over the weekend, and Monday we can

10  address this issue.  This issue doesn't need to be done today.

11          MS. BROWN:  That's fine, Your Honor.  I agree.

12          THE COURT:  Would you agree with that?

13          MS. BROWN:  I agree a hundred percent.  I just need

14  it for closing.

15          THE COURT:  But I also agree it's confusing where I'm

16  like, please tell me there are no additional documents,

17  because if they are, I don't want to deal with this next week.

18          MS. BROWN:  Of course.  And I will represent we have

19  done everything, Your Honor, and I will triple the --

20          THE COURT:  I know, I know.  To be candid, some of

21  your due diligence hurts Janssen's prior lack of due

22  diligence.

23          MS. BROWN:  No kidding.

24          THE COURT:  So this is where we are.  Right?  I know.

25      But look, I've also been trying to be careful about not
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 1 │ insinuating that trial counsel has been the one that has been
 2 │ responsible --
 3 │          MS. BROWN:  I know.  Listen, I --
 4 │          THE COURT:  -- and I've done my best to do that.
 5 │          MS. BROWN:  I thought your statement of a tragedy was
 6 │ accurate.
 7 │          THE COURT:  But let me tell you this:  We're going
 8 │ to -- all right.  So here's where we are.  I'm reserving.
 9 │ You'll confirm by Monday.
10 │          MS. BROWN:  Yes, sir.
11 │          THE COURT:  And then Monday we have some very brief
12 │ argument on whether -- well, one, I presume your argument,
13 │ Mr. Wirmani, is going to be none at all; but if so, redacted
14 │ just to Murphy, correct?
15 │      And yours is going to be all of it --
16 │          MS. BROWN:  We've got an inference on these
17 │ documents --
18 │          THE COURT:  -- if not the redacted document, but it's
19 │ the inverse.
20 │          MS. BROWN:  Yeah.
21 │          THE COURT:  All right.  Look, we are taking a little
22 │ bit of a longer break here, but I won't give them a second.
23 │          MS. BROWN:  I appreciate it.  Thank you.
24 │          (Sidebar was concluded at 2:51 p.m.)
25 │          (A short recess occurred.)
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 1          THE COURT:  Ms. Kaucher, I am going to dismiss you, but

 2   I have to do it in front of the jury.

 3          THE WITNESS:  It's okay.

 4          THE COURT:  Okay?  So just bear with the formality of

 5   it, but I don't like them coming in and just saying, where did

 6   the witness go?

 7       So, Kim, go get them?

 8          THE DEPUTY COURT CLERK:  Yes.

 9          THE COURT:  All right.

10          MR. MARKETOS:  Your Honor --

11          THE COURT:  Oh.

12          MR. MARKETOS:  It's fine.  I may have one issue

13   before Dr. Jena testifies.

14          THE COURT:  Sidebar, or can it wait --

15          MR. MARKETOS:  It can be a sidebar, yeah.

16          THE COURT:  Or do you want me to leave the jury out?

17          MR. MARKETOS:  No, it can be a sidebar.

18          THE COURT:  Okay.

19          MR. MARKETOS:  That's fine.

20          THE COURT:  And then we have some stuff at 5 o'clock

21   to chat about.

22          MR. MARKETOS:  Yes, Your Honor.

23          THE COURT:  All right.  So you guys have to stick

24   around just for a little bit.

25          THE DEPUTY COURT CLERK:  All rise.
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1   (The jury enters the courtroom.)

2   THE COURT: All right, folks. Everybody have a seat.

3   And I didn't want to dismiss the witness without you

4 folks here.

5   But, Ms. Kaucher, you are excused from the trial.

6 Thank you.

7   THE WITNESS: Thank you.

8   THE COURT: And we're back to Janssen's case,

9 correct?

10   MS. BROWN: Yes, Your Honor.

11   THE COURT: Ms. Brown, who are you all calling as the

12 next witness?

13   MS. BROWN: Your Honor, we call Dr. Jena to the

14 stand, please.

15   THE COURT: All right.

16   Dr. Jena, she has to swear you in.

17 (**DR. ANUPAM JENA**, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED

18 AS FOLLOWS:)

19   THE DEPUTY COURT CLERK: Please state your name and

20 the spelling of your last name for the record.

21   THE WITNESS: Anupam Jena, A-N-U-P-A-M, as in Mary,

22 Jena, J-E-N-A.

23   THE COURT: All right. Doctor, have a seat.

24   Ms. Brown, when you're ready to proceed, you may.

25   MS. BROWN: Thank you very much. Good afternoon,

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 1   everyone.

 2   (DIRECT EXAMINATION BY MS. BROWN:)

 3   Q.   Good afternoon, Dr. Jena.

 4   A.   Thank you for having me.

 5   Q.   Thanks for coming.

 6   Dr. Jena, before we get into things, would you just

 7   take a minute to introduce yourself to our jury?

 8   A.   My name is Anupam Jena. I go by Bapu, B-A-P-U. It's

 9   nice to meet you. Sorry to keep you here on a Friday

10   afternoon, but I'll try to make my comments engaging.

11   Q.   All right. Let's do it.

12   Can we start learning a little bit about your

13   qualifications and your education. You are both a medical

14   doctor and a Ph.D. economist.

15   Is that right, Dr. Jena?

16   A.   That's correct. I studied economics at the University of

17   Chicago. I went to medical school there. Before that, I

18   graduated from MIT, which is now almost 25 years ago, in 2000.

19   I studied biology and economics. And here I am now.

20   Q.   I understand, Dr. Jena -- correct me if I'm wrong -- but

21   this combination of a medical degree and Ph.D. in economics is

22   pretty rare.

23   A.   Yes. It's uncommon. There's maybe ten people in the

24   country that have an M.D. and a Ph.D. in economics. I don't

25   know if that's a good thing or a bad thing, but it is a thing,

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         1 | so it's not common.

         2 | Q.   It's your thing?

         3 | A.   It's my thing, yes.

         4 | Q.   Okay.

         5 | Tell us, with both a Ph.D. in economics and a medical

         6 | degree, tell us a little bit what you do now.

         7 | A.   So my primary job is I'm a professor at Harvard

         8 | University. I spend most of my time in Harvard Medical

         9 | School. I do research in a lot of different areas, which we

        10 | can talk about. So that's sort of my full-time job.

        11 | I also see patients at Massachusetts General Hospital.

        12 | We call it MGH or Mass General. It's one of the big teaching

        13 | hospitals in the Boston area. I work there as an inpatient

        14 | general medical doctor, so I'm there several weeks a year,

        15 | working with resident physicians -- these are trainees --

        16 | seeing people coming to the hospital with things like

        17 | pneumonia, complications from HIV, heart problems, breathing

        18 | problems, kidney problems, those sorts of things.

        19 | I also teach undergraduates at Harvard College, a

        20 | course on health care policy. I teach Harvard medical

        21 | students, and I teach Harvard graduate students. So that's

        22 | sort of my academic life. In addition to that, I am a writer.

        23 | I have a podcast called Freakonomics M.D., and that's how I

        24 | spend my time.

        25 | Q.   All right.

          1   Let's talk a little bit. You have received certain

          2   rewards and honors over the course of your career.

          3   Correct, Dr. Jena?

          4   A.   That's correct. And it was not my idea to pick this

          5   slide, by the way.

          6   Q.   I made you do it.

          7   Let's just talk -- I know we have a slide after this

          8   about one of your TEDMED presentations, but just tell us, I

          9   guess: What's been the most sort of importance to you on this

         10   slide to talk to our jury about?

         11   A.   I'd say on the slide maybe two things I would point out.

         12   The first is the second one that says "NIH," National

         13   Institutes of Health. In 2013, I was the first social

         14   scientist -- economics is a social science -- I was the first

         15   social scientist to win what's called the Early Independence

         16   Award. It was an award given to people who are ready to

         17   launch their careers in academics. I was going to be a health

         18   economist and a physician. And that award was to study what I

         19   would call the economics of physician behavior to try to

         20   understand why it is that physicians do what they do, to sort

         21   of elucidate all those factors. So that's something that I'm

         22   proud of, I guess.

         23   Q.   So, Dr. Jena, one of the issues in this case that our

         24   jury is going to be asked to consider is kind of that very

         25   thing, whether promotional marketing causes a physician to

1   prescribe a medicine.

2   Is that an area that you have particularly focused some

3   of your studies on?

4   A.   I'd say yes. There's so many things -- and we'll talk

5   about this -- that affect what a physician does. Their

6   training, the patient that they see obviously is really

7   important, who their colleagues are, what they learn from

8   scientific journals. All these things affect not only

9   prescribing decisions but whether or not to perform a surgery

10 or not to perform a surgery, whether to order a diagnostic

11 test, to get an MRI. These are all decisions that doctors

12 make, and hundreds of decisions every day. What is it that

13 drives them to do what they do? That's part of my area of

14 research.

15 Q.   And is it part, in fact, of what we asked you to look at

16 and talk about here in this case?

17 A.   Yes, it is.

18 Q.   All right.

19   You mentioned that you've written some books, and we

20 have one of them right here, *Random Acts of Medicine,* and this

21 was actually written up in the *Wall Street Journal,* right,

22 Doctor, a review of it?

23 A.   It was. Don't make me read, please, what it says there,

24 but yes.

25 Q.   Is says here you're "an overachieving economist and

 1 physician."

 2   Right, sir?

 3 A.   Yes, that's correct.

 4 Q.   All right.

 5   Just tell us a little bit. What is this book about?

 6 A.   This book is about how chance affects your life. You

 7 know, it's not surprising to think that a lot of things affect

 8 us that we can't control. You know, you're walking across the

 9 street or a loved one is walking across a street, they get hit

10 by a car. That's totally chance. It's totally random. You

11 can't predict it. You couldn't have seen it coming. Someone

12 develops cancer but they don't have any risk factors for

13 cancer. Something they couldn't have seen coming. It's

14 random.

15   But there are a lot of things that happen in our lives

16 that are random but that can teach us something, that we can

17 kind of see if we look at it in the right way, and this book

18 goes through a lot of really interesting examples from my

19 research about how chance occurrences affect our life and what

20 we can learn from them.

21 Q.   Okay.

22   One of things you've done as it relates to some of the

23 issues we're going to talk about in this case, you have

24 presented to other groups of doctors and scientists and

25 interesting folks -- interested folks on some of the topics of

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1   your research.

2   Correct?

3   A.   Both interesting and interested, both, yeah, yeah.

4   Q.   And we have a short clip, with the Court's permission, I

5   want to play from this TEDMED talk because it relates to some

6   of the things you're going to talk about here.

7   Is that right, Doctor?

8   A.   Yes.

9   MS. BROWN: Your Honor, do I have permission?

10   THE COURT: Counsel, any objection?

11   MR. MARKETOS: No objection.

12   THE COURT: All right. So you may.

13   MS. BROWN: Okay. Thanks.

14   Could we play that? Thank you.

15   (Video clip played at this time.)

16   BY MS. BROWN:

17   Q.   Dr. Jena, why did you want to put this particular clip in

18   our presentation here today?

19   A.   I put it here because the issues that are being brought

20   up here are really interesting. Right? They feel intuitive

21   to us. You have seen some data that suggests certain things

22   might be true. And that's true of a lot of things that we

23   think about and encounter in our lives, and in research,

24   that's what we're often faced with. Could this be right?

25   Could this be wrong?

1   And the point of this clip, and we'll talk a lot about

2 this, is that when you look at data, you have to be very

3 careful and thoughtful about what you're seeing because

4 there's a lot of ways to interpret what you see, and some of

5 those interpretations might be wrong and some of them might be

6 right. And hopefully what we can do together in our time

7 together is try to understand, okay, if you have data that's

8 presented to you, how do you analyze it? How do you think

9 about it? Is it the right data? Is it the right approach?

10 That's what I hope we'll be able to do together.

11 Q.   This idea, Dr. Jena, of seeing and looking, is it

12 something that you have researched and that we have two

13 articles here about?

14 A.   It is, yes. A lot of what I do is use very large data to

15 try to understand questions at the intersection of medicine

16 and health and economics, and I use tools from a field that I

17 am an expert in which is called causal inference. How do you

18 demonstrate that something causes something else to happen?

19 May seem like an obvious thing, but it's not obvious when

20 you're looking at data because data can be messy, the patterns

21 may not quite make sense. You have to have a framework for

22 figuring out what is causing what in those data.

23   So the second study that's on this page is something I

24 just mentioned to you, and it's from a story about my wife,

25 and I talked about it at the beginning of the TED Talk. My

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 1   wife is running a race in Boston. It was her first time

 2   running this race. It started in the Seaport area. It went

 3   through the hospital area where I work, which is called Mass

 4   General, and then it went to Cambridge, which is where Harvard

 5   University is located, and it went back.

 6   It was her first time running this kind of race, so she

 7   wanted me to watch her on the race route. So I said I'm going

 8   to watch her on the race route. What do I do? I drive to

 9   Mass General, because I had a parking space there. And I'm

10   driving on the main thoroughfare, and the road is blocked. So

11   I turned around and I went home. And I told her hours later,

12   I'm sorry that I couldn't see you at the race because I

13   couldn't get to MGH. She says, Well, what happened to

14   everybody that needed to get to the hospital that day? So

15   that was sort of a casual observation that she made, and we

16   were able to analyze the data in a rigorous way. A study came

17   -- our study came out in *The New England Journal of Medicine*

18   just a week before the Boston Marathon, and it sort of

19   illustrated how you can use patterns that might feel intuitive

20   -- it was an idea that my wife brought up, it was an

21   interesting idea that you can study in a rigorous way.

22   So that's the first example. The second one is also

23   one that I think is quite interesting. I don't know if any of

24   you have children, if any of you have family members or

25   friends with ADHD. We have a study that showed that children

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 1   who are born in August are about 30 percent more likely to be

 2   diagnosed with ADHD than children who are born in September.

 3   Think about why that might be true for a second.  I live in

 4   Massachusetts.  In Massachusetts, the date is September 1 for

 5   entering into kindergarten.  If you're born before

 6   September 1, you can enter kindergarten when you're five years

 7   old.  If you're born on, let's say, September 4th, you've got

 8   to wait a year.  And so you enter kindergarten basically when

 9   you're six years old.

10        And what happens is that in any kindergarten class, the

11   kids who have August birthdays are almost a year younger than

12   the kids who have September birthdays.  And being a year

13   younger at that age it's like -- that's, like, 20 percent less

14   time on planet Earth.  So it means a lot at that point.

15        And the behaviors are different and the kids are more

16   likely to be diagnosed with ADHD not necessarily because they

17   have it, they may or may not, but it's just that they're

18   younger.  They're less mature relative to their peers.

19        So, again, an example of you can use big data to try to

20   unpack questions that are important to people.

21   Q.   Is it also, Dr. Jena, an example of how you might look at

22   just -- just -- if you're just taking a quick look at the

23   data, you might think, well, there must be something about

24   being born in August that causes ADHD, but that wouldn't be

25   right?
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1   A.   Exactly. You need to know the mechanism, unpack why --

2   why it's happening. And in this case, we show that it's

3   because of this very arbitrary thing which is a state, like

4   Massachusetts, says you have to be five by September 1. In

5   other states, it might be December, and it would be a

6   different finding in those states.

7   Q.   Okay.

8   Doctor, in addition to your research, your work at the

9   hospital, your teaching, your podcast, your writing, do you

10 also, from time to time, do expert witness work like you're

11 doing here today?

12 A.   I have been able to do that for the last five or six

13 years.

14 Q.   Okay.

15   Are we compensating you for your time doing that here?

16 A.   Yes, you are.

17 Q.   All right.

18   And have you been engaged to work on this case for a

19 number of years now?

20 A.   I have, yeah. I think -- I was just looking over the

21 initial report I filed in this case. It was in 2019, and I

22 remember I was supposed to be deposed. This is when lawyers

23 ask you questions about your report. And it was right before

24 the COVID-19 pandemic, so I think it got postponed.

25   So this -- my -- my involvement here is a long time,

 1   actually.

 2   Q.   Okay.

 3   Can you estimate generally, you know, just give us a

 4   ballpark, how much compensation have you received for the

 5   years of work you've put on this case?

 6   A.   Sure. I think several hundred thousand dollars, yeah,

 7   easily.

 8   Q.   Okay. Let's talk about what we asked you to do.

 9   Can you walk us through what we asked of you, and then

10   we'll talk about what you found.

11   A.   Good.

12   So let me sort of orient you to the questions that I

13   was asked to answer, and I've kind of put them into three

14   buckets just to make it very -- very easy for us to think

15   about.

16   So the first is you've heard a lot about conduct by

17   Janssen. The first question I was asked, did the conduct by

18   Janssen cause doctors to write more prescriptions for these

19   two drugs, Prezista and Intelence? More prescriptions than

20   they otherwise would have? That's the first question.

21   And to break that question down, it's useful just to

22   think about what do you need and how do you analyze things

23   that you need.

24   So the first is the data. What data do you need? That

25   was the first question.

1   And the second is how do you analyze the data? All

2   right.

3   The second question is I was asked to review a report

4   by a Professor Shaked. He's a professor at Boston University.

5   I'm also in Boston. And I was asked to look at his findings

6   and offer an opinion about whether or not I thought the

7   analyses were correct.

8   And Professor Shaked has presented to you, I think, a

9   damages number of several hundred million dollars of economic

10   harm to the government, and I was asked to offer an opinion

11   about whether or not those damages were supported, whether

12   they were reliable or correct.

13   Q.   Okay.

14   And to answer some of these questions, Dr. Jena, did

15   you have access to the same data that Dr. Shaked had access to

16   for his opinions?

17   A.   Yes.

18   Q.   All right.

19   And are you prepared to answer these questions and help

20   us understand your analysis and your work in this case?

21   A.   Yeah. I'd be happy to, and I hope that -- we'll do it

22   together. I want everybody to understand exactly how I was

23   thinking about these issues.

24   Q.   All right.

25   To start, why don't you give us a summary of what your

 1   ultimate conclusions were as it relates to these three

 2   questions.

 3   A.   Sure.

 4   So the first opinion is that the data, the data that

 5   were obtained, the data that were analyzed by the plaintiffs'

 6   experts, in my opinion cannot show that Janssen caused

 7   physicians to write more prescriptions for these two drugs.

 8   There is a data problem. The data are insufficient to

 9   show what they believe that it can show.

10   Q.   Are we going to go through those reasons today?

11   A.   We definitely will, yes. I don't know how exciting it

12   will be, but we will.

13   Q.   Okay. All right.

14   What's your second summary there, Dr. Jena?

15   A.   So the second relates to the analyses. So you start with

16   the data, and then you have to analyze the data. And my

17   opinion is that Professor Shaked's analysis, the way that he

18   analyzed the data, also does not show that Janssen led

19   physicians or caused physicians to prescribe more of these

20   drugs. That's the second opinion.

21   And the third one ties it all home because this is a

22   case where damages to the government have been argued, have

23   been alleged.

24   And putting those first two things together, the third

25   opinion is that Dr. Shaked, or Professor Shaked's, analyses on

 1 the damages don't show any economic harm to the government.

 2 Q.   Okay.

 3   This is a slide, Dr. Jena, that Dr. Shaked showed our

 4 jury when he was here titled "Off-Label Damages from 2006 to

 5 2014."

 6   Do you see that, sir?

 7 A.   Yes, ma'am.

 8 Q.   Okay.

 9   And have you taken a look at this as well as part of

10 your testimony coming here today?

11 A.   Yes, I did.

12 Q.   All right.

13   What is important about the data, if anything,

14 contained on this slide as it informs your opinion?

15 A.   I think that two things are important. The first is it

16 is useful to level-set. Sometimes when we talk about numbers

17 and money, it's easy to lose sight of the magnitudes that are

18 involved. So I think this slide does a good job of

19 illustrating what are the magnitudes that are involved.

20   The government spent more than $2 billion total on

21 these two drugs.

22 Q.   Is that the -- I'm sorry to interrupt you, Dr. Jena.

23   Is that the yellow circle on the outside?

24 A.   Exactly.

25   So you see it says, "All government P&I," that's

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 1  Prezista and Intelence, "RX," is a shorthand for prescription,

 2  "sales of $2.95 billion."  So close to $3 billion.

 3        So that's the total spending, just to level-set.  Lots

 4  and lots of money being spent.

 5        The second thing is that blue circle.  It says

 6  "Off-Label P&I."  So off-label Prezista and Intelence

 7  prescriptions.

 8        So what Professor Shaked has done, along with some help

 9  from others, is to try to identify prescriptions that he

10  believed to be off-label.  And I'll talk about, you know, what

11  that means and whether I agree with it in a moment.  That's

12  that blue box -- or blue circle, and then inside that is a red

13  circle.  And it says, "Off-Label Prescriptions Initiated," or

14  started "By Influenced Physicians."  These are physicians that

15  Professor Shaked believes were influenced by the different

16  things that Janssen was doing.

17        And the off-label damages that he puts forward are

18  $446.7 million there.

19        And so I'll pause there, but there's another thing I'd

20  like to say just to orient you to the blue and red, but let me

21  just pause for a second.

22  Q.   Yeah.  Let me follow up with two questions, and then I'll

23  let you add anything.

24        Are the off-label damages of $446 million just a

25  portion of the total damages that Dr. Shaked presented to our
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1 jury?

2 A.   That is correct. They are portions.

3 Q.   All right.

4   Are there also another bucket of damages that we're

5 going to talk about today?

6 A.   Yes.

7 Q.   All right.

8   Second question for you, Dr. Jena, is what, if

9 anything, do we know -- when we look at the blue circle, which

10 seems to be larger than the damage circle -- what do we know

11 about whether or not the government has records of paying for

12 off-label medicines for Prezista and Intelence?

13 A.   It tells you two things. One is literally that: That

14 the government has paid for -- and just to be clear, when I

15 say "off-label," I'm not endorsing that it's off-label. I

16 would say "off-label" in quotation marks. But just to keep it

17 easy for the court reporter and all of you, that's -- just

18 preface that.

19   So the government is paying and has paid for these

20 off-label prescriptions. So that's the first thing that you

21 need to keep in mind.

22 Q.   Are they -- and where we see that they've paid in that

23 blue circle, are those physicians who Janssen had contact

24 with?

25 A.   No. They are not.

1 Q.   Okay.

2   What does that tell you?

3 A.   Well, what that tells me is the following, right. So the

4 concern here is that Janssen was interacting with doctors in

5 ways that it shouldn't have. And that doctors were

6 prescribing drugs that they wouldn't have or that they

7 shouldn't have.

8   One way to think about whether or not that makes sense

9 is to say, All right. Well, let's look at doctors who had no

10 interaction with Janssen, who are not, quote-unquote,

11 "influenced" in any way. That's what's happening in that blue

12 circle.

13   What you can see is that these doctors are still

14 writing prescriptions for these two drugs. And you have to

15 ask yourself, well, why are they writing prescriptions for

16 these two drugs if they weren't told to do so in some way by

17 Janssen? The short of it is, they're writing prescriptions

18 for these drugs because they believe that the drugs actually

19 work for the patients that they're treating.

20 Q.   Dr. Jena, you have had the opportunity over the course of

21 your career to write prescriptions for patients.

22   Is that right?

23 A.   Yes.

24 Q.   And have you, over the course of your career, prescribed

25 a medicine off-label?

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1   A.   Yes.   It's very common.   I would guess, just

2   statistically, all of you in this room, or many of you in this

3   room, have probably received a medication that was

4   quote-unquote, "off-label."

5   Q.   And when you have done that, sir, as a medical doctor,

6   writing an off-label prescription for a patient, why are you

7   doing that?

8   A.   You're doing it because you've got the patient's interest

9   in mind.   Right?   So someone comes to you, they've got a

10   medical problem, and you're trying to figure out what's

11   causing that problem and how do you treat it.

12   Sometimes we're lucky enough to have medications that

13   we know work.   They're on-label.   But other times there's

14   medications that are not on the FDA label but, nonetheless,

15   there is scientific evidence that is out there, clinical

16   trials, clinical studies that tell us, as doctors or your

17   nurse practitioner or physician assistant, that this

18   medication will likely work, and doctors like me prescribe it.

19   And that's important because you don't want to withhold

20   a medication from somebody if it works simply because it

21   hasn't been FDA approved yet.   Because literally the day

22   before a drug gets FDA approved, it's effective.   You wouldn't

23   want to withhold a drug from a patient for a reason like that.

24   Q.   Okay.

25   Let's start, Dr. Jena, if we could, with how you got to

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 1   some of the summary opinions we just reviewed, and let's start

 2   with this first question.

 3   Okay, Dr. Jena?

 4   Did our alleged improper promotion cause doctors to

 5   prescribe Prezista and Intelence in a, quote, "off-label" way?

 6   Okay?

 7   And before we do that, you mentioned you're sort of

 8   assuming these categories are, in fact, off-label for purposes

 9   of your opinion.

10   Correct?

11   A.   That's correct.

12   Q.   Okay.

13   But, for example, is prescribing Prezista to a patient

14   with a lipid condition off-label?

15   A.   I would say no, for two reasons.

16   One is that if you look at the label for Prezista --

17   MR. MARKETOS: Your Honor, I object.

18   May I approach?

19   THE COURT: You may.

20   (Sidebar begins at 3:38 p.m.)

21   MR. MARKETOS: Here we go, Your Honor. This is an

22   economic expert who is here to testify about causation and

23   damages, and they're going to try to backdoor an opinion on

24   whether or not a Prezista prescription and the label is

25   medically necessary. So that's what he's going to do.

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 1          This witness is only on economics and damages.  They do

 2   not have an expert on whether a Prezista prescription or an

 3   Intelence prescription is medically reasonable or necessary,

 4   and that's what he's about offer.

 5          MS. BROWN:  It's not at all, and it's just one

 6   question, Your Honor, and it's disclosed in his report that he

 7   is assuming that this is, quote-unquote, "off-label."  And

 8   it's not uncontroversial because their own expert --

 9          THE COURT:  Let me look at the question for a moment,

10   please.

11            (Brief pause.)

12          THE COURT:  He gave an opinion as to what's

13   off-label.

14          MS. BROWN:  Yes, Your Honor, because he's a medical

15   doctor and they don't dispute it.  I mean, this is the fact of

16   the case --

17          THE COURT:  No, they do -- they don't dispute?

18          MS. BROWN:  That we -- hold on a second.

19          THE COURT:  What?  Let me look at the question.  Did

20   you see the question you just asked?

21          MS. BROWN:  I do.  Can I just explain?

22          Prescribing Prezista to someone with a lipid condition

23   is not off-label.  And Dr. Glatt admitted that clear as day

24   because it's the truth.  I mean, that is -- I'm not going into

25   the other claims, which everyone agrees are off the label,
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 1  but --

 2          THE COURT:  Hold on.

 3          (Brief pause.)

 4          THE COURT:  And so I disagree with you.  You asked

 5  him, is prescribing Prezista to someone with lipid issues

 6  off-label.

 7          MS. BROWN:  Right.  Nobody --

 8          THE COURT:  That is in dispute.

 9          MS. BROWN:  It is not.  Their claim is that it's

10  misleading, but nobody disputes it's not off-label including

11  Dr. Glatt, who testified to it under oath.  It's -- it's not

12  --

13          THE COURT:  What does this have to do with his

14  testimony on the causation of damages?

15          MS. BROWN:  Yeah, but --

16          THE COURT:  I'm inclined to agree to strike this last

17  question and response.

18          MS. BROWN:  Here's why, Your Honor, and he just said

19  it.  When he refers throughout this presentation to off-label,

20  he is accepting those categories as off-label --

21          THE COURT:  Right.

22          MS. BROWN:  -- even though he doesn't agree --

23          THE COURT:  Yes.

24          MS. BROWN:  -- and they don't either because it's in

25  a footnote in Shaked's --
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1   THE COURT: Look, I don't mind him taking assumptions

2   on facts like every other expert does. He doesn't get to give

3   his opinion on those facts. He can say, look, I'm not here to

4   testify about whether this is off-label or not. I'm taking

5   these assumptions from Janssen and then I'm --

6   MS. BROWN: No, it's not from me.

7   THE COURT: -- or from Relators -- and then I'm

8   applying, you know, the math and saying, I disagree with

9   Dr. Shaked's testimony. And that's where he's limited to.

10   I agree with Mr. Marketos. You can't backdoor him to

11 give additional testimony on off-label and all of the other

12 things. It's -- his testimony is basically matched up to

13 Shaked's and I guess Dew's, which is, I accept these

14 assumptions either from Relators or Janssen, however your

15 testimony is going to come out, and, Based on those

16 assumptions -- and I'm not opining on those. Based on those

17 assumptions, let me talk to you about the methodology and the

18 math that was done by Dr. Shaked and how that's not correct.

19   So I'm going to strike the last question and response,

20 and you're going to have to have him testify within that scope

21 of causation and damages piece only.

22   (Sidebar was concluded at 3:42 p.m.)

23   (Open court.)

24   THE COURT: All right, folks. There was an

25 objection. I did sustain the objection, so the last question

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 1   and response I'm just going to strike. You're not to consider

 2   the last response from the witness and then we'll proceed.

 3   Ms. Brown, whenever you're ready.

 4   MS. BROWN: Thank you, Your Honor.

 5   BY MS. BROWN:

 6   Q.   Dr. Jena, for purposes of your discussion and for

 7   purposes of your analysis, are you -- you have off-label in

 8   quotes here. Tell us just about what assumption you're making

 9   as we move through your analysis.

10   A.   I am -- so Dr. Shaked and the gentleman named Mr. Dew

11   used data to identify prescriptions that they characterize as,

12   quote-unquote, "off-label." And they're sort of clinical

13   reasons why we might disagree about that, and I would say that

14   I do disagree with it --

15   MR. MARKETOS: Your Honor. Your Honor.

16   THE COURT: The objection is sustained. Strike that

17   last response.

18   BY MS. BROWN:

19   Q.   And, Dr. Jena, that is my fault. Bad question.

20   Just tell us, have you made an independent

21   determination about this off-label, or are you assuming based

22   on the analyses that were done by Dr. Shaked?

23   A.   I'm using that assumption from them, period.

24   Q.   Okay. Perfect.

25   So let's start with some of the things you considered

1   in answering this first question.

2   Okay? Okay.

3   The first slide we have talks about the data that you

4   had available to you. And let me first ask you, Dr. Jena,

5   we're going to talk a little about CMS data and what it is.

6   Have you ever used CMS data before?

7   A.   I have. I've probably published maybe 20 to 30 studies.

8   The marathon study that we spoke about in the *New England*

9   *Journal of Medicine* was published using CMS data. I use it

10   quite a bit.

11   Q.   Okay.

12   Where does CMS data come from?

13   A.   So let me describe it to you. I don't know if you've

14   heard or have a feel for what date claims data is. Any time

15   you go to a doctor, let's say you walk into your doctor's

16   office because you have stomach pain. Your doctor spends some

17   time with you. They touch your abdomen, they listen to your

18   lungs, listen to your heart, they listen to your stomach.

19   They maybe get some laboratory tests. Maybe they get an X-ray

20   of your stomach or a CT scan of your stomach. They make a

21   diagnosis, and then they ultimately prescribe you a

22   medication.

23   So that's sort of the clinical thing that you would be

24   familiar with.

25   But on the back end, there's a lot of billing that

        1   happens around all the care that was provided to you that you

        2   received. So you saw the doctor. The doctor bills your

        3   insurance company for that visit, the time spent evaluating

        4   you. If your insurer is Medicare, your doctor sends a bill to

        5   Medicare.

        6   Your doctor ordered that laboratory test. That

        7   laboratory test is separately billed. There is a claim that

        8   is sent to the insurance company, in this case Medicare, for

        9   that laboratory test.

       10   You went to the pharmacy to fill a prescription for the

       11   medication. When you go to the pharmacy, you pay a co-pay for

       12   that drug, or maybe you don't pay a co-pay, the pharmacist

       13   gives you that medication. The pharmacist and the pharmacy

       14   send a bill to the insurance company. That's a claim. That's

       15   a transaction that you picked up that prescription medication

       16   and it's time now for the insurance company to pay you.

       17   So that is what claims data is. It's sort of billing

       18   transactions that give you a snapshot into some of the things

       19   that you're experiencing when you have a medical problem.

       20   That's what the data is.

       21   Q.   Okay.

       22   And maybe this is obvious because it's called CMS data,

       23   but does it come directly from CMS, the government agency that

       24   reimburses for some of these medicines?

       25   A.   Yeah. The ultimate data that was analyzed comes from

1   CMS.

2   Q.   Okay.

3   Are there limitations to the CMS data?

4   A.   There are limitations. I should say there are strengths

5   and limitations. I've published a lot of studies using CMS

6   data, Medicare data, so I understand what it can be used for

7   and it can be powerful in a lot of ways, but there are a lot

8   of limitations.

9   If it's okay, I can walk us through what some of those

10   limitations are.

11   Q.   Sure.

12   And did you help put together this slide to kind of

13   identify what you have and what you don't have?

14   A.   Yes.

15   Q.   Okay.

16   Help explain that to us, if you could, Dr. Jena.

17   A.   Okay.

18   So claims data, this is billing data. It just says

19   what was billed on your behalf for care that you received.

20   That's all it is. Okay?

21   So it has billing codes. It often has patient and

22   physician information. You, as a patient, received care from

23   Dr. Thomas. Dr. Thomas bills the insurer. The insurer knows

24   that you are the patient and that Dr. Thomas provided the

25   care. That is what's encapsulated in these data.

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 1            What is not included in this data is quite a bit.  So

 2   the claims data that you've heard about, these are not patient

 3   medical records.  So, for example, if you came to your doctor

 4   with an abdominal pain, nowhere would it say whether you had

 5   abdominal pain before.  Nowhere -- the medical record would

 6   say that.  It wouldn't say that in the claims.

 7            Your medical record would say whether you've tried

 8   other medications before.  That might not be present in the

 9   insurance data if you changed insurers.

10            So there's a lot of detailed patient medical record

11   information that is not in the claims.

12   Q.   Dr. Jena, let me ask you:  One of the issues in our case

13   or one of the alleged off-label uses has to do with dose,

14   whether Intelence was being dosed once a day or twice a day.

15            Does CMS get information on dose when it decides

16   whether or not to reimburse a medicine like Intelence?

17   A.   CMS does not get information on dose, and it is not in

18   these data.

19   Q.   Okay.

20            Another issue on both Prezista and Intelence is whether

21   a patient was treatment-naive or treatment-experienced.

22            Does CMS have data like that to evaluate that question?

23   A.   CMS would often not have data on that to evaluate that

24   question because you need to know the medical history of

25   someone to truly know whether or not they are treatment-naive
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 1 | or treatment-experienced.

 2 | Q.   So what do you have? You have a list here of a lot of

 3 | different things that it does not contain.

 4 | What does it contain?

 5 | A.   Really what it contains is information on who the patient

 6 | is, who they saw, what medical care they may have received.

 7 | And not all Medicare, but the items that the medical

 8 | providers, whether it's the hospital, the physical therapist,

 9 | the pharmacist, would have billed for. So it's limited in

10 | that way.

11 | Q.   And does this apply both to Medicare and Medicaid, or is

12 | this just one of them?

13 | A.   This is both.

14 | Q.   Okay.

15 | What about something called ADAP?

16 | First of all, what is ADAP?

17 | A.   ADAP is AIDS Drug Assistance Program. So people who are

18 | living with HIV will often get insurance through Medicare or

19 | Medicaid, which is a state program, and then there are people

20 | who get insurance through this program called ADAP as well for

21 | drug coverage.

22 | Q.   All right.

23 | Did you have a chance to look at and review the ADAP

24 | data as well in this case?

25 | A.   I did.

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1   Q.   Are there similar limitations to that data?

2   A.   There are similar limitations to that data, and let me

3   just say the following: The CMS data that I just spoke about,

4   that's voluminous. There's a lot of data. You do require

5   computers to analyze that data. The ADAP data that we are

6   talking about here you can download on your phone right now.

7   So there's a big difference between those types of data.

8   The second thing is is that there's a lot of

9   limitations. It doesn't have any of the granularity. It does

10 not have any of the granularity that the CMS data has. All

11 that it has is spending in a quarter of a year on specific

12 drugs. That's all it has.

13 Q.   Does the ADAP data allow you to identify whether or not a

14 physician who wrote a prescription for Intelence or Prezista

15 had any contact with Janssen?

16 A.   It does not. So it does not tell you who the physicians

17 are. It does not tell you who the patients are. So you do

18 not know when a patient saw a doctor. You cannot link that

19 information in any way to any contact by Janssen. So there's

20 no granularity in these data at all. It is impossible to say

21 that a doctor was seen by a drug rep or received a message and

22 prescribed a drug because that granularity is not there in the

23 data.

24 Q.   We saw in Dr. Shaked's report and also when he was here

25 testifying that he attributed $83 million in the damages to

1   ADAP payments. How could he do that or did you understand he

2   did that if there's no data on the physician who wrote the

3   prescriptions?

4   A.   The way he does that is he extrapolates. He says ADAP is

5   a public program. Patients with HIV are getting drugs covered

6   through this program. Although he does not have information

7   on patients, although he does not have information on specific

8   drugs provided on specific dates or information on who the

9   prescribers are, what he says is, all right, well, if I know

10   that in the first quarter of 2012 this much money was spent in

11   this program on Prezista and Intelence, maybe I can just use

12   data from somewhere else like Medicaid to extrapolate what the

13   spending was by ADAP. So he's doing what's called an

14   extrapolation, but he doesn't have any actual data on those

15   different elements that are required to show that it's

16   happening.

17   Q.   What information would you want to know before you did an

18   extrapolation like that?

19   A.   So the core thing that you need to know before you do any

20   sort of extrapolation is you need to make sure the populations

21   are comparable. So, for example, if you've heard the phrase

22   "apples-to-apples comparison" or "apples-to-oranges

23   comparison," which is not a good comparison, you need that to

24   be the case. And let me give you an example so it's easier.

25   My parents came to this country from India many years ago in

1 the 1960s. If I were to go to India and have the ability to

2 measure in one billion people who had had malaria and who had

3 not had malaria and then I said to myself, I got a billion

4 data points. I know very well who has got malaria. Can I

5 extrapolate that to Princeton, New Jersey, to say what

6 percentage of people have malaria? You think on that, you sit

7 on that and you say, no, that doesn't make sense, even if you

8 have a billion data points, because it's not apples to apples.

9 The populations aren't comparable. So you need have ADAP be

10 comparable to Medicaid.

11 Q.   And based on what you know about ADAP and Medicaid data,

12 is that an apples-to-apples comparison?

13 A.   No, it's not an apples-to-apples comparison. The

14 programs are very different. The characteristics of the

15 patients are very different.

16 Q.   You mentioned in your example you have a million or a

17 billion data points on folks in India. We've heard a lot

18 about the law of large numbers and how if you just have a

19 really, really big dataset, you get a reliable result.

20   Is that right?

21 A.   That's not right. In fact, that's -- I think the malaria

22 in India example is a good one. You can have one billion data

23 points, but it doesn't answer the question of what is the rate

24 of malaria in Princeton, New Jersey, or where I live in

25 Wellesley, Massachusetts. I don't know if you've seen the

1   movie Spider-Man. What is the phrase? "With great power

2   comes great responsibility." It's like with big data comes

3   big responsibility -- it's not exactly, but the point is you

4   can't solve every problem by having a lot of data.

5   Q.   All right.

6   Let's talk about pharmacy data. We also heard that

7   part of what Dr. Shaked relied on was some data from three

8   pharmacies, and let me -- before we get to your analysis of

9   that data, let me just ask you: Why can't we get this

10 information from the CMS data? Why do we need pharmacy data

11 at all?

12 A.   Good question. So this relates to an allegation about

13 dosing. So the drug Intelence, the allegation is that doctors

14 were led to believe that they could prescribe it to be taken

15 once daily as opposed to multiple times daily. CMS data does

16 not have any information on dosing. They don't pay -- or ask

17 for any information on dosing when they make those payments.

18 So it's not in those data. So Plaintiffs had to look

19 elsewhere.

20 Q.   Okay.

21   And here with this pharmacy data we also heard, well,

22 it's a lot. Law of the large numbers. We got a lot of

23 pharmacy data, so we know we are getting good information from

24 the pharmacy data.

25   Do you agree with that?

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1   A.   I would say no.

2   Q.   Why is that?

3   A.   The reason why is, again, it goes to extrapolation. If

4   you have data from Walgreens, Rite Aid, BioScrip, you say, all

5   right, I want to look at the patients who filled prescriptions

6   with these pharmacies and measure how often the doctor wrote a

7   dosing instruction that said, take this once daily, and then

8   you want to extrapolate that to a different population, what

9   do you need to be able to make that extrapolation? What do

10   you need? You need apples to apples. The populations have to

11   be comparable, so you have to be able to show that. That's

12   the first point.

13   The second point is you also have to have the right

14   data elements to be able to use it in the right place.

15   Q.   So to that point, this is, as you know, Dr. Jena, a case

16   about reimbursement by the government, right? When I look at

17   your chart, the Walgreens data appears to not even be able to

18   tell us if the government paid for the medicine.

19   Is that right?

20   A.   That is correct, yes.

21   Q.   So the data that Dr. Shaked relies on as it relates to

22   Walgreens doesn't have information about the patient and

23   doesn't have information about the payor?

24   A.   That is correct. So there's no way to know from the

25   Walgreens data who paid for the drug, whether the patient paid

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1   out of pocket, whether the government paid, whether Aetna, a

2   commercial insurance paid. You don't know.

3   Q.   And then as it relates to the Rite Aid data, it looks

4   like we don't know who prescribed the medicine.

5   Is that right?

6   A.   That is correct.

7   Q.   And as to the BioScrip data, we don't know the patient.

8   We don't know if the government paid, and we don't know when

9   the prescription was written.

10   Is that also right?

11   A.   That is correct. And both that and the inability to

12   measure the physician in Rite Aid pose really significant

13   problems.

14   Q.   All right.

15   So if we look at this here, did you try to create a

16   summary of these data deficiencies that are part of your

17   opinion?

18   A.   Yes.

19   Q.   Can you summarize for us why you believe this data is

20   insufficient to reach the conclusions Dr. Shaked does?

21   A.   Sure. Just to reorient us, I want to talk to you about

22   data and how you analyze data. The data are insufficient.

23   The starting point, let's talk about what is the -- what are

24   the concerns that have been brought here. The concerns are

25   that doctors are being interacted with by Janssen drug

1 representatives, being told improper messages about lipid

2 profiles, about dosing. So you want to know whether or not

3 doctors who have been, quote-unquote, influenced in some way

4 or paid by Janssen prescribed differently than doctors who

5 didn't get those messages or who weren't paid. So for the

6 messages you do need to know what messages were told to a

7 doctor. If I could give an analogy, it's like if you have a

8 clinical trial, you want to figure out whether or not the drug

9 that you are taking works for you or not. Obviously, what you

10 do is you take a lot of people. You give some of them the

11 drug, and you give other people a placebo, no drug. And then

12 you measure the response to the drug. What's being done here

13 is like saying, Let's figure out what the effect of this drug

14 is, but, by the way, I don't really know who got the drug.

15 That's what we're talking about here. So it is important to

16 be precise about what messages -- what people received.

17 That's the only way you can study the byproducts of those

18 messages. That's the first row there.

19 Q.   It looks like some of the data were call notes, but they

20 don't show the messages that are being analyzed.

21   Is that right?

22 A.   That is correct.

23 Q.   All right.

24   And the speaker programs, they don't -- the data

25 related to the speaker programs doesn't show these messages

 1 | that are being evaluated.

 2 | Is that right?

 3 | A.   Correct. You need to know -- so doctors will often go as

 4 | attendees to speaker programs where they learn about the

 5 | different attributes of a drug, how safe it is, how effective

 6 | it is, what other treatments might be out there. So you have

 7 | to show that the content the doctors were receiving was

 8 | inappropriate, and that has not been shown.

 9 | Q.   Okay.

10 | And as to the CMS data, the pharmacy data, and the ADAP

11 | data, did you just review the limitations you identified in

12 | those data?

13 | A.   Yes.

14 | Q.   All right.

15 | Let's move on from big data not solving the problems to

16 | prescriber factors.

17 | What is that, and how does it impact your opinions

18 | here?

19 | A.   So one of the areas I spent a lot of time in my research

20 | is to try to understand what is it that drives physicians to

21 | treat patients in the way that they do. So when we think

22 | about drug decisions, so what drug does your doctor prescribe

23 | you? Do they prescribe you Lipitor or Crestor or Zocor?

24 | Those are cholesterol medications. Those are prescription or

25 | prescribing decisions that were made by the person taking care

 1   of you. So what are the factors that affect a prescriber's

 2   decision? That's what prescriber factor means.

 3   Q.   All right.

 4   Obviously, in this case, we are talking about two HIV

 5   medicines.

 6   Is there something about HIV specifically that is

 7   important to understand before evaluating prescribing factors?

 8   A.   Yeah. Absolutely. So as you asked me about how I spend

 9   my time, so I see patients at Mass General. I work in the

10   hospital setting. So I will sometimes see patients come into

11   the hospital who have either a new diagnosis of HIV or

12   complications of HIV. And I might be able to start the

13   process of treatment, but this is definitely an area where I'm

14   going to involve an infectious disease specialist and, in

15   particular, HIV specialist. The care of patients who have HIV

16   is highly specialized. The doctors have lots of training and

17   experience, so that's an important factor to keep in mind when

18   you think, all right, a doctor has been visited by a drug rep.

19   Is it likely that someone with that much experience, seeing

20   patients, spent a lot of time training, would be influenced?

21   Maybe; maybe not. You got to think about whether or not

22   that's possible.

23   The other thing is that doctors review evidence,

24   clinical trials, scientific studies, clinical guidelines. So

25   that's an important feature as well. And there's other things

1   here that I am happy to talk to about.

2   Q.   We heard, actually, from Dr. Rosenberg, who also works at

3   Harvard and Mass General, similar institutions as you, and he

4   told us about testing a patient's blood before prescribing

5   medicine and about follow-up tests to check on whether the

6   medicine is working.

7   Did those factors influence or affect your analysis of

8   this question in our case?

9   A.   They absolutely do. The reason why is because, as we

10   kind of continue to talk with each other, the thought that I

11   want you to have in your mind is, when I hear a prescription

12   was written by a doctor for Prezista and Intelence, was that

13   prescription written because the doctor was influenced in some

14   way by Janssen, or was that prescription a result of any

15   number of other factors? One factor that you have to keep

16   front and center in your mind is maybe the prescriptions are

17   being written because the drug is working for the patient.

18   How do you know that the drug is working for the patient?

19   Well, sometimes it's symptoms. My headaches are better. My

20   chest pain is less frequent. In HIV, it's things like viral

21   load. It's things like cholesterol panels. We can see,

22   because we have the laboratory test to do so, whether or not

23   the drug is effective. We can see, because we have the lab

24   studies to do so, whether or not there are problems emerging

25   with a patient's cholesterol or lipids. That's what the test

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 1 allows you to do, make sure patients --

 2   MR. MARKETOS: Your Honor. Objection.

 3   May we approach?

 4   THE COURT: You may.

 5   (Sidebar begins at 4:03 p.m.)

 6   MR. MARKETOS: He's now going into his role as a

 7 doctor and what they see in HIV patient and lipids. This

 8 gentleman is here on economics and causation. He did not

 9 testify about clinical. He is not giving a clinical opinion

10 in this case, and he did not even rely on Dr. Rosenberg's

11 opinion in this case. He is now testifying about what we see

12 in the labs, and he's going into his doctor role.

13   MS. BROWN: And we sort of anticipated this kind of

14 objection, Your Honor. We sourced all of the slides with the

15 cites to the affirmative report, so we can pull the

16 affirmative report right there. To move things along, I will

17 rephrase to make sure we are keeping this to exactly what's in

18 the report as it is on the slide, but this is one of the

19 factors that he considered in evaluating whether you have to

20 consider the expertise of the physician in HIV. This is one

21 of his major analyses and critiques of Dr. Shaked, is that

22 once you consider the expertise of the physician, this alleged

23 correlation between Janssen and prescriptions goes away. So I

24 can rephrase. This is disclosed. The cite is there.

25   THE COURT: Well, how are you going rephrase it?

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1   MS. BROWN: I am going to say, What I want to focus

2   you on is what was important to your economic analysis of the

3   question you were asked to identify. Is the -- nature of HIV

4   treatment by specialized doctors important? He will say yes.

5   We will move on.

6   THE COURT: All right.

7   MR. MARKETOS: Your Honor, may I respond very

8   quickly. So you know where this is going. Absolutely, he can

9   talk about he takes into account guidelines in his confounding

10   factors, what was disclosed, that doctors take that stuff into

11   account. What he's doing is delving into his own clinical

12   experience, talking about his own experience, this what we see

13   in the lab. Now he is going into doctor land, and that is not

14   the subject matter.

15   THE COURT: I don't want him going to that. I want

16   him to stay on the damages and the causation. He is not here

17   as some medical expert to talk about lipids and cholesterol

18   and all the other things.

19   MS. BROWN: He is not, Your Honor. What he's giving

20   is the fact that was given on this page of his report that

21   this is important to analyze in the prescribing --

22   THE COURT: What is important?

23   MS. BROWN: The fact that HIV requires specialists to

24   treat. That's the analysis. The major analysis we are

25   working up to is --

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 1              THE COURT:  If you want to elicit that one response

 2   and then move on, I'm going to allow that, Mr. Marketos.  Not

 3   much more than that.

 4              MR. MARKETOS:  Yes, Your Honor.  And his last

 5   response was not that.  His last --

 6              THE COURT:  I know.  I'm going to strike the last

 7   response.

 8         I'm going to have you rephrase and do exactly what you

 9   told me you were going to do.

10              (Sidebar begins at 4:05 p.m.)

11              THE COURT:  I'm striking the last response and then

12   we are going to proceed.  I sustained an objection.

13         Ms. Brown, you can proceed with those directions.

14              MS. BROWN:  Thank you, Your Honor.

15   BY MS. BROWN:

16   Q.   Dr. Jena, I want to focus on just the facts that informed

17   your analysis of the damages.

18         Does that make sense to you?

19   A.   Okay.

20   Q.   I understand the first is considering who the doctors

21   were who treat HIV patients.

22         Correct?

23   A.   Yes.

24   Q.   And is the second considering how HIV is treated by

25   specialists?
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 1   A.   Yes.

 2   Q.   And, finally, that doctors are making patient-specific

 3   decisions.

 4        Is that right?

 5   A.   Correct.

 6   Q.   Let's talk next about what factors impact a medical

 7   decision of a doctor.

 8        Okay, Dr. Jena?

 9   A.   Perfect.

10   Q.   All right.

11        This is a chart from your -- or graphic from your

12   expert report.

13        Can you orient and just help us understand what we're

14   looking at here?

15   A.   Sure.  This is a list of a lot of different factors that

16   might impact what medication a doctor chooses for a patient.

17   Q.   Okay.

18        And we're going to work through them sort of sections

19   at a time.  The first that we have identified here are

20   physician characteristics.

21        What do you mean by that?

22   A.   Physician characteristics include things like where your

23   doctor trained, whether they specialize in a particular area.

24   Did they specialize in infectious disease?  Do they specialize

25   in HIV?  That's the sort of thing that's encompassed by
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 1 physician characteristics,

 2 Q.   Okay.

 3   And one of the things that's already in evidence and

 4 our jury has seen is something called the government

 5 guidelines for the treatment of HIV.

 6   Are you familiar with those, sir?

 7 A.   Yes, ma'am.

 8 Q.   Okay.

 9   And what the government says is that "Multiple studies

10 have demonstrated that better outcomes are achieved in

11 HIV-infected outpatients cared for by clinicians with HIV

12 expertise."

13   Do you see that?

14 A.   Yes.

15 Q.   And how, if at all, does this factor into your analysis

16 of damages in this case?

17 A.   This factors in because it illustrates how experience

18 matters for HIV care and how experience of a physician might

19 be relevant for the medications that they choose.

20 Q.   Okay.

21   And do you have an example here that you can take us

22 through about how to consider and evaluate the experience of a

23 physician?

24 A.   Yes. This is just one example. This is a physician

25 named Dr. David Ferris. He's an HIV specialist. He has over

1   20 years of experience treating HIV patients. He's prescribed

2   many thousands of HIV drugs, and the question for me is

3   whether or not when I see a prescription that is attributed to

4   Janssen's conduct, might it instead be attributed to the fact

5   that this particular physician has decades of expertise, has

6   seen many, many patients with HIV?

7   Q.   All right.

8   Let's talk about another factor. Drug-specific

9   factors.

10   What are those, Dr. Jena?

11   A.   Drug-specific factors are a lot of different things. So

12   is the drug safe or how safe is it? Does it have side

13   effects? How efficacious is it? What is the clinical data

14   that supports the use of the drug? Lots of different factors

15   are drug-specific and are considered when a doctor makes a

16   decision.

17   Q.   Okay.

18   Let's start -- let's talk about Prezista first and then

19   Intelence.

20   What are we looking at here, and how does it inform

21   your consideration of drug-specific factors?

22   A.   So what we're looking at here is a timeline. On the

23   bottom axis, the x-axis, that's years. On the y-axis, or the

24   horizontal axis, that's number of prescriptions, and this is

25   for the drug Prezista. All that I'm showing here is that the

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 1  science around that drug evolved rapidly over time.  So we're

 2  looking from 2006 to 2014, about eight years.  Many, many

 3  studies coming out about this particular drug.  This is the

 4  type of information that physicians and prescribers would be

 5  aware of and could drive a prescription decision.

 6  Q.   Okay.

 7       On here it looks like some of the boxes that you have

 8  on here reference label changes.

 9       Is that right, Doctor?

10  A.   That is correct.

11  Q.   I also see you have on here some updates to the

12  government guidelines.

13       Correct?

14  A.   That is correct.

15  Q.   And then other general scientific articles and advances

16  during this time period?

17  A.   Correct.

18  Q.   All right.

19       And is the same true, Doctor, for Intelence?  What are

20  we looking at here?  Prescriptions increasing?  What's

21  happening in the science?

22  A.   The science is also evolving over time.  This is a place

23  where doctors are looking at new science, and if I observe a

24  prescription to be written, is it because there's new science

25  that has evolved or something else?
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1 Q.   Okay.

2   Let's talk about patient characteristics.

3   What are the patient characteristics that you want to

4 consider when evaluating why a physician makes a prescribing

5 decision?

6 A.   So there's a lot of different patient characteristics.

7 So, for example, we're talking about HIV drugs, so you want to

8 know whether or not a person who is on an HIV drug has had

9 challenges with prior treatments. Have they become resistant

10 to prior treatments? Have they developed side effects with

11 particular treatments? Those are treatment-specific factors

12 for the patient.

13   You want to know whether or not the drug is working. I

14 mentioned viral load earlier. There are lab tests that can be

15 used to measure whether the drug is working. That is a

16 patient-specific factor.

17 Q.   One of the patient-specific factors you have on the chart

18 from your report is payor formularies and policies.

19   What is that?

20 A.   Payors refer to insurance companies, so, for example, in

21 Medicare, people who have Medicare Part D, it's insurance

22 coverage for drugs. There's a lot of different Part D health

23 plans or Part D sponsors, and they might have different

24 formularies and policies for payment.

25 Q.   And is that part of a patient-specific characteristic

1 that has to be considered?

2 A.   Yes.

3 Q.   Okay.

4   You spoke about checking to see how a medicine is

5 working as a patient characteristic. How do the blood tests

6 inform that?

7 A.   There's lots of different ways that you can assess

8 whether or not a drug is working for a patient with HIV. You

9 can look at the CD4 count. That is a measure of the immune

10 system function. If that level is low, that means the immune

11 system function is low. The virus is taking a toll.

12   You can look at the viral load. Essentially, how much

13 HIV virus is replicated in the body. If that number is high,

14 then that means the treatment is not working.

15   You can look at drug resistance. You can look at

16 things like cholesterol panels to see if there are side

17 effects that are developing.

18   So that's the way that tests can be used to tell you if

19 a patient is responding to therapy and what are the side

20 effects they may be developing.

21 Q.   All right.

22   This, Dr. Jena, is a particular patient that comes out

23 of the data you looked at.

24   Correct?

25 A.   Correct.

1 Q.   And you have it titled "Timeline of Selected Medicare" --

2 I think we have a typo -- "Patients' HIV Prescriptions."

3   What are we looking at and how does it inform these

4 individual patient prescription decisions?

5 A.   So remember the story I told you earlier about how

6 billing data comes to be: You see a doctor, you get a lab

7 test, you go to the pharmacy, you get a prescription. That's

8 really encompassed here.

9   So this is an individual patient, it's a real-world

10 patient who has taken multiple different therapies, both

11 within the class called PIs, protease inhibitors, as well as

12 other drugs. They have gone from one therapy to the other

13 over time. They are at many times on multiple therapies.

14   And then that top thing that says, "Tests: Viral

15 Load," that's each of the times in which they had their viral

16 load checked to make sure that the drugs were working

17 appropriately.

18 Q.   So let me ask you then, Dr. Jena, for all of these, kind

19 of, colored bars that we see, does that indicate that the

20 patient was taking that medicine at that time?

21 A.   That does. It indicates that they were going to the

22 pharmacy, filling prescriptions for the drug at that time.

23 Q.   Okay.

24   And what are all the white breaks in some of the lines?

25 A.   Those breaks are -- let's say your prescription -- you

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 1 | were going to fill it on August 3rd for your August
 2 | prescription.  But if you went there on July 31st to fill it
 3 | in advance, it would just show up white for that month because
 4 | you just got it a couple days early.
 5 | Q.   And if I understand you, these black circles at the top
 6 | show, at least in the government data, every time a physician
 7 | ordered a test to check on whether or not these medicines were
 8 | working?
 9 | A.   Correct.
10 | Q.   Okay.
11 |      How does this, everything we see on this chart, how
12 | does that influence what you're analyzing here?
13 | A.   Because it comes back to the core question.  What is the
14 | core question?  The core question is if I see a prescription
15 | for Prezista and Intelence, what caused that prescription to
16 | be written?  Was it conduct by Janssen?  Was it the fact that
17 | the drug was working?
18 |      And this is the rubric, this is the way that you can
19 | see that everything is there to be able to figure out whether
20 | drugs work or don't work, whether they generate side effects
21 | to lipids or other things.  You have that ability, in the real
22 | world, CMS, Medicare, Medicaid knows that, and we can see that
23 | in the data.
24 | Q.   Does the CMS data give you information about how long
25 | patient were on their medicines when they got reimbursed?
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1 A.   It does. And it does have that information, and that's

2 important because it's an indicator for two things. It's an

3 indicator for whether or not a drug is working. So if

4 someone's on a drug, an HIV drug for six months or more, what

5 does that mean? It means it's probably working. How do you

6 know that? Because you can check the viral load, you can

7 check the lipids, you can check other blood markers to know

8 that it's working.

9   It's relevant because the vast majority of

10 prescriptions that we're talking about here, the spending, is

11 in that category for patients who are on these drugs for a

12 fair amount of time. More than six months. So it indicates

13 that that patient experience matters. The drugs were working

14 for them.

15 Q.   So this is data that we have cited in your report that

16 comes from the government data you looked at.

17   Is that right?

18 A.   That is correct.

19 Q.   And what is this pie chart telling us as it relates to

20 this issue of were the drugs working?

21 A.   So the 80.5 percent, that blue area that's a big part of

22 the pie, this is government reimbursement. It's the

23 percentage of spending. 80 percent of government

24 reimbursement was for patients who are using Prezista for more

25 than six months. And the remainder, 19 percent, for patients

 1 who are using it less.

 2   So what that means is that about 80 percent of the

 3 time, we're talking about patients who are on a drug that was

 4 working. And that is relevant because of the core question.

 5 If a patient is on a drug, is it because of the conduct that

 6 they -- that their doctor, rather, might have experienced from

 7 Janssen, or is it because of this factor? The factor is that

 8 the drug is working.

 9 Q.   Is there also data within this government data that you

10 looked at about patients who may have switched to Prezista or

11 Intelence because another medicine was causing side effects?

12 A.   There is the ability to be looking at some of that new

13 data.

14 Q.   Okay.

15   And do we have here -- if we look down on the bottom,

16 have we taken an individual doctor who prescribes to an

17 individual patient to give an example of what exists in the

18 data?

19 A.   Yes. I'm happy to walk you through what this shows.

20 Q.   Would you please do that, Dr. Jena?

21 A.   Sure.

22   So this is a real live patient treated by a doctor.

23 This is a patient who was on a drug called Reyataz. That's a

24 protease inhibitor. It's in the same class as Prezista. At

25 some point in 2013, the fall of 2013, we can see from the

1 billing data that CMS has provided that this patient developed

2 a condition called jaundice -- it's essentially a problem with

3 the liver where the skin and the eyes start to turn a little

4 bit yellow -- and then the person switched. The doctor

5 switched them to a different drug, Prezista.

6   That's what's being shown here.

7 Q. Okay.

8   And this individual claim that we're looking at here

9 was -- totaled about $13,000 in Dr. Shaked's damages model.

10 Do you have a sense of how much we're talking about for all of

11 the patients that have data like this indicating a switch for

12 side effects?

13   MR. MARKETOS: Objection, Your Honor. Undisclosed.

14   THE COURT: I lost my feed.

15   Sidebar.

16   (Sidebar begins at 4:19 p.m.)

17   MR. MARKETOS: Let me explain it to Your Honor. He's

18 sourcing to Professor Shaked's report here, and now he's going

19 to give an undisclosed calculated guess --

20   THE COURT: Let me hear first.

21   MR. MARKETOS: An undisclosed calculation about

22 what -- he's taking one example, and now he's going to give an

23 undisclosed calculation, does she have a sense from the

24 data -- does he have a sense from the data about all the

25 Prezista prescriptions where somebody was switched from

1   Reyataz.

2   THE COURT: Is that coming next?

3   MS. BROWN: It's not going to be a precise number,

4   Your Honor. It's a general figure. We're talking about a

5   couple of million dollars. This is from Dr. Shaked's report.

6   He identifies 209 in Exhibit 26, including this particular

7   example, and if you multiply this by 209, you got about $3

8   million.

9   This is data from their expert that he looked at and

10 disclosed.

11   MR. MARKETOS: No. That last part is the part he

12 didn't do.

13   THE COURT: Which part, the math?

14   MR. MARKETOS: The part about disclosing that he is

15 tabulating something that he claims from Dr. Shaked's report

16 and equals a Prezista switch from Reyataz.

17   He's got a rebuttal report and it's not in there. He

18 never did this calculation. He never made this claim.

19   THE COURT: Is this calculation -- where is this

20 calculation written?

21   MS. BROWN: It's not -- it's 209 of these, including

22 this one, are identified in Exhibit 26 of Dr. Shaked's report.

23 He is just going to say he reviewed it. They know it because

24 it's in his report, and they produced that report to us.

25   All he's saying is giving a sense of what we're talking

 1 about. This is not insignificant. You have 209 of these.

 2 This is several millions of dollars where there's data to

 3 indicate the reason for the prescription wasn't us, it was

 4 jaundiced from another medicine.

 5   MR. MARKETOS: Your Honor --

 6   MS. BROWN: It's their expert's report.

 7   THE COURT: No, I want to hear you out, but I

 8 understand.

 9   Mr. Marketos?

10   MR. MARKETOS: So he does a rebuttal report. There's

11 even a supplemental report that comes after that. What

12 they're now doing is taking arguments from our expert's

13 affirmative report, and he's making new claims about them that

14 were not disclosed in his rebuttal report.

15   If it were there, it would be sourced, and she could

16 point it out to me.

17   MS. BROWN: It is sourced.

18   THE COURT: In his own report?

19   MS. BROWN: No, it's sourced in the report that he

20 looked at that their expert --

21   THE COURT: That's not what I'm saying. No, no.

22 Listen to what I'm saying. Where in Dr. Jena's report is this

23 calculation?

24   MS. BROWN: Well, this calculation is -- the math is

25 not there. The two numbers are there --

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 1              THE COURT:  Then it's out.

 2              MS. BROWN:  -- and you just have to multiply them

 3  together.  I mean, he doesn't have to do every machination of

 4  the numbers.  When they came in here with Dr. Shaked's report,

 5  he took data and made a reasonable inference based on his

 6  methodology from the data.

 7              THE COURT:  If this was so critical that he was

 8  testifying to, why isn't it written down in anything that he

 9  produced to the Relators?

10              MS. BROWN:  Dr. Jena?

11              THE COURT:  Yes.

12              MS. BROWN:  This is in his report.  This idea of

13  switches for side effects are in his report.  The example is

14  coming from Dr. Shaked's report.

15         I don't need him to do the math.  I'm just going to

16  move on.

17              THE COURT:  Then I'm going sustain it.

18              (Sidebar was concluded at 4:22 p.m.)

19              (Open court.)

20              THE COURT:  All right.  Just hold on one moment,

21  folks.

22         So the objection is sustained.

23         But you're going to proceed in a --

24              MS. BROWN:  I am.

25  BY MS. BROWN:
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1 Q. Dr. Jena, did you evaluate the CMS data to identify

2 examples like this one that we're talking about?

3 A. Yes.

4 Q. All right.

5   Let's talk about manufacturer-related factors. What

6 are those, and how did you consider them?

7 A. So this is case about a particular -- one aspect of this

8 case is about a particular form of marketing which is

9 considered off-label or improper marketing. So it's important

10 to think about manufacturers and their marketing as well.

11 Because could that affect physician prescribing? Yes, it

12 could.

13   So in this case here, there's a lot of different drug

14 companies that produce HIV drugs. And they are all marketing

15 towards different physicians. So it's important to think, is

16 it possible? Absolutely. But you have to analyze it on a

17 case-by-case basis.

18 Q. Okay.

19   And in terms of your review of Dr. Shaked's analysis as

20 it relates to all of these different factors, did he consider

21 all of these different factors that could influence a

22 prescriber's prescribing decision?

23 A. No. Professor Shaked only looks at one factor. He looks

24 at a factor which is Janssen's marketing and a particular

25 aspect of Janssen's marketing. He doesn't consider any of the

 1 other factors that could lead doctors and likely lead doctors

 2 to prescribe the drugs that they do.

 3 Q.   Okay.

 4   And did he make certain assumptions that we're going to

 5 talk about?

 6 A.   Yes.

 7 Q.   What are those, Dr. Jena?

 8 A.   I think the two assumptions are as follows:

 9   He assumes that every single contact between a Janssen

10 drug rep and a doctor was improper, that it contained

11 off-label messages. There's multiple different off-label

12 allegations here; all of those off-label messages were

13 contained. That's his assumption. Without proof.

14   The second is that he assumes, as I kind of allude to

15 in this funnel chart, that 100 percent of the time that

16 marketing is what causes the "off-label," quote-unquote,

17 prescriptions to occur. Meaning it's not any of these other

18 factors, it's just marketing. That's what he assumes.

19 Q.   Okay.

20   We are going to talk about Professor Shaked's analyses

21 and your analysis of his analyses.

22   Okay?

23   So let's start with the comparisons that Professor

24 Shaked makes. What are they, and how do you look at them?

25 A.   So at a really high level, and just more to unpack, but

1   at a really high level, he basically makes a simple

2   comparison. And simple in the following sense.

3   He takes doctors and he puts them into just two

4   categories. There are doctors who are influenced. Maybe they

5   were influenced because they attended an event where another

6   doctor was speaking to them about a drug, maybe they are,

7   quote-unquote, "influenced" because they were visited by a

8   drug rep who spoke to them about off-label messages.

9   So he just divides doctors into two categories,

10   influenced and noninfluenced, or I have here, speaker and

11   nonspeaker. That's it. A comparison of doctors in these two

12   categories, and he looks at their prescribing. That is the

13   analysis.

14   Q.   Okay.

15   And what are the two sort of categories of issues that

16   you have with those analyses?

17   A.   I think that there's two broad issues I have. The first

18   I would put into the bucket of what I might call errors, and

19   I'll describe to you what I mean in a moment.

20   And the second is assumptions. Assumptions that he

21   makes that I disagree with.

22   And the way I would describe this is, you know, if

23   you're doing a math problem, there might be multiple different

24   ways that you can solve that math problem. You might have to

25   make some assumptions to solve it, some may be better than

 1   worse, but if at some point in your math problem you're saying

 2   to yourself, ten plus ten equals 25, that's an error. That's

 3   not a matter of just the right or wrong assumption. That is

 4   an error.

 5   So there's errors that he makes and there are

 6   assumptions that he makes, and I want to talk to you about

 7   what both of those are.

 8   Q.   Okay.

 9   And we're going to start with calculation errors.

10   Is that right, sir?

11   A.   Yes, ma'am.

12   Q.   Okay.

13   Tell us what we're looking at and how we're going to

14   start walking through some of the calculation errors, please,

15   Dr. Jena.

16   A.   Sure.

17   So one of the numbers that you saw earlier from

18   Professor Shaked was a comparison of doctors who are contacted

19   and a comparison to those are who are not contacted. And what

20   he showed you was that the quote-unquote, "off-label" rate was

21   22.3 percent. That's that blue bar among contacted

22   physicians. And it was 11.2 percent among non-contacted

23   physicians. So that's what he showed you.

24   There is a way that he went about computing that number

25   which is important to talk about as well.

1   Q.   Okay.

2   And did you help put together a graphic, that we hope

3   you can take us through to help us understand that calculation

4   error?

5   A.   I did, yes.

6   MS. BROWN: And Your Honor, could Dr. Jena have

7   permission to come down and, sort of, point us through this

8   example?

9   THE COURT: Yeah. There's no objection, I presume?

10   MR. MARKETOS: No objection, Your Honor.

11   THE COURT: All right. You may, Doctor.

12   BY MS. BROWN:

13   Q.   Okay.

14   Dr. Jena, help us understand this error in the -- and

15   just so I understand it, Dr. Jena, you're about to tell us we

16   saw from Dr. Shaked that there is a difference between the

17   prescriptions of doctors who were contacted by Janssen and

18   those were not.

19   Right?

20   A.   Correct.

21   Q.   Okay.

22   And your opinion is there is a calculation error that

23   led to that difference.

24   Is that right?

25   A.   That's correct.

1 Q.   Okay.

2   And you're going to help us understand that now.

3 A.   Yeah.

4 Q.   Okay.

5 A.   So before I show you this schematic -- so can I go back

6 and forth like this?

7 Q.   Yep.

8 A.   Okay.

9   So let me just describe to you what Professor Shaked

10 does in this analysis. So his, sort of, thought experiment is

11 that there is a doctor who is responsible for initiating a

12 patient on a course of therapy. So if I'm a patient and I go

13 see a doctor, that doctor treats me. Let's say they prescribe

14 Prezista; the prescription's for me as a patient from that

15 doctor. Professor Shaked attributes to that doctor -- if I as

16 a patient move on to a different physician in the future, and

17 I continue to be prescribed that same medication, what

18 Dr. Shaked says is those prescriptions, even though written by

19 a different physician, should be attributed to this first

20 physician that I saw. What I would call the initiating

21 physician or the initiator.

22   And that principle would apply for on-label or

23 off-label prescribing, both the same. The idea is that the

24 doctor who you see who starts you down a path of care --

25   THE COURT: Ms. Brown, if the witness is going to be

 1   outside of the witness box, he needs to do something other

 2   than just do what he's doing now. Otherwise, I'm pulling him

 3   back in the box.

 4   MS. BROWN: Yes, yes. Understood, Your Honor.

 5   BY MS. BROWN:

 6   Q.   Dr. Jena, do you want to get to the --

 7   THE COURT: Point at something or laser something --

 8   MS. BROWN: Okay. We're here. We're here.

 9   THE WITNESS: This is complicated. I apologize,

10   Your Honor.

11   MS. BROWN: Yep.

12   THE WITNESS: So this is a box. You see at the top

13   left, you see influenced prescriber. Bottom left, you see

14   non-influenced prescriber. These are two doctors. There are

15   two patients: patient 1, patient 2. The influenced

16   prescriber is the one who is first seeing patient 1 and

17   patient 2.

18   So in Professor Shaked's way of thinking, this doctor

19   is the initiator. They initiate patient 1 on two off-label

20   prescriptions. They initiate patient 2 on three on-label

21   prescriptions. Those are the yellow vials.

22   All right. Now look at the second row. What happens

23   to this patient? The patient switches doctors. So that's

24   what's happening here. They are now seeing a different

25   doctor. This doctor is non-influenced. Have not had any

1   interaction with Janssen.

2   The patient is continued on their medication. So

3   patient 1 continues with three off-label prescriptions written

4   by that second doctor. Patient 2 continues with two more

5   prescriptions, written by that second doctor. All right?

6   That's the story.

7   Now, what does Professor Shaked say we should do to

8   attribute these prescriptions to the right physician? So what

9   he says is, remember, the prescriptions that started with the

10   initiator are always going to be attributed back to the

11   initiator. So patient 1 ultimately had five off-label

12   prescriptions. They are attributed to the influenced

13   prescriber. Patient 2 ultimately had five on-label

14   prescriptions. They are attributed to the influenced

15   prescriber.

16   Now, how does Professor Shaked say that he should

17   calculate the off-label rate? You just take the number of

18   off-label prescriptions, which is five, and you divide it by

19   the total number of prescriptions, five plus five is ten.

20   That is 50 percent.

21   So in Professor Shaked's model, he says that the

22   off-label rate should be 50 percent for the influenced

23   prescriber. This prescriber here is irrelevant. That's why I

24   have a dash mark here. They don't even get considered in the

25   analysis. Why is that? It's because it's not the initiating

 1 physician. They weren't the one that made the decision to

 2 start the patient.

 3   So that's what Professor Shaked said he was going to

 4 do.

 5 BY MS. BROWN:

 6 Q.   Why does that matter, Dr. Jena?

 7 A.   Let me show you why that matters, and here is where the

 8 error comes in. What did he do?

 9   So what he did is he forgot. He made an error. He

10 forgot to move these two prescriptions from patient 2 and

11 nonprescriber to the prescriber who started this whole

12 process. These two yellow prescriptions, if you follow

13 Professor Shaked's logic, should be up here, but they are not.

14 So what happens?

15   When he goes to calculate his off-label rate, how does

16 he calculate it? He says five off-label prescriptions. One,

17 two, three, four, five. Divided by what? Five plus three.

18 Five divided by eight. Eight prescriptions he attributes to

19 this doctor, five of which are off-label, that gives you an

20 off-label rate of 63 percent.

21 Q.   So, Dr. Jena, just before you keep going, the difference

22 between the first model and this model is 13 percent?

23 A.   Correct.

24 Q.   Okay.

25 A.   It's 50 percent as it should have been --

1 Q.   Yep.

2 A.   -- but what he says it is is 63 percent. He made an

3 error.

4 Q.   Okay.

5 A.   Now the second doctor.

6   The second doctor was a non-influenced prescriber.

7 They never started the patient on either one of those

8 therapies, so they shouldn't have been in the analysis. But

9 guess what? They end up in the analysis. They end up in the

10 analysis because he said that there are two prescriptions that

11 are attributed to this doctor. How many off-label? None. So

12 what is this doctor's off-label rate in his calculation? It's

13 zero percent. But this doctor should not have been in the

14 data.

15   So let me show you why this matters. It matters for

16 two reasons. One, 63 is higher than 50. So his calculation

17 error leads to an off-label rate that is 13 percentage points

18 too high. That's the first problem.

19   The second is you're comparing the influenced doctors

20 to what? To the non-influenced doctors. So you need to make

21 sure that you get the off-label rate correct for the

22 non-influenced doctors.

23   What he does is he attaches a value of zero percent to

24 all of these non-influenced prescribers. So it drives down

25 the off-label rate for non-influenced prescribers

1 inappropriately low. And here is where this takes us. All

2 right.

3   This is what I just showed you. 22.3 percent was what

4 he calculates for contacted physicians' off-label rates, 11.2

5 percent for non-contacted physicians. That is a difference of

6 about 11 percent.

7 Q. Dr. Jena, is that where we started, that graph on the

8 left? Is that where we started with Dr. Shaked saying that

9 there's about 11 percent difference between people who had

10 contact with us and people who didn't?

11 A. That is exactly where we started. That is the number

12 that you saw earlier as well.

13 Q. Okay.

14   And then what happens on the right?

15 A. So what happens if you correct it? If you correct it,

16 there is no more difference between the contacted and the

17 non-contacted physicians.

18   So let me just say this again. You saw earlier,

19 Professor Shaked showed you earlier, that contacted physicians

20 had higher rates of off-label prescribing than non-contacted

21 physicians. What I'm telling you here now is that was a

22 calculation error. That was a ten plus ten equals 25. That's

23 just an error. It's not a matter of disagreement about

24 assumptions. It's an error.

25   If you correct that error, the off-label rate is the

1 same between the contacted and the non-contacted physicians.

2 Q.   Thank you, Dr. Jena.

3   All right.

4   Dr. Jena, we spoke about the error, and I recall the

5 other issue that you wanted to talk about, not just a

6 calculation error, but an issue with the assumptions.

7   Is that right?

8 A.   That's correct.

9 Q.   Okay.

10   So talk to us about the assumptions that are at play

11 here that Dr. Shaked makes.

12 A.   So there's a few different assumptions. The first

13 assumption is that he assumes that every point of contact with

14 the doctor was a problem, that there were, let's say,

15 off-label messages that were offered to the doctor 100 percent

16 of the time. So he assumes that. That's an assumption that

17 he makes.

18   And the second thing is remember that funnel plot where

19 these -- all these different factors that affect prescribing?

20 He assumes that the only factor that mattered is the one at

21 the top, which is marketing. So 100 percent of prescriptions

22 were caused by marketing, and that's it.

23 Q.   Why is that important, Doctor?

24 A.   Well, it's important because it's not a -- it's not a

25 sort of -- you can't assume away the finding. What you've got

1   to do is analyze the data, be thoughtful about all the

2   possibilities that explain prescribing, and then make an

3   analysis.

4   Q.   Okay.

5   What about as it relates to speakers? What assumption

6   does Dr. Shaked make there?

7   A.   So Dr. Shaked makes this assumption which is that as soon

8   as a speaker received payment from Janssen, from that point

9   on, every single prescription that that doctor wrote, every

10 single prescription that that doctor wrote was a result of

11 that speaker payment. It wasn't a result of the drugs

12 working. It wasn't a result of a patient switching because of

13 jaundice or some other side effect. It wasn't a result of the

14 patient failing multiple therapies and therefore ending up on

15 Prezista. It was a result of the speaker payment.

16   To put that into perspective, I have a big timeline

17 here. His analysis, the assumption he makes is that if a

18 program happened in 2006 where a speaker got, let's say, one

19 payment and didn't write a prescription for two years but

20 then, let's say, in 2010 or 2011, four or five years later

21 wrote a prescription, he would say that that prescription and

22 every single prescription that that doctor wrote was because

23 of the payment that happened five years ago.

24   That is an assumption that he makes.

25 Q.   Okay.

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 1        How does that -- how does this idea, the idea that

 2  correlation doesn't equal causation, how does that affect the

 3  assumptions we just talked about?

 4  A.   Well, when you're analyzing data -- and this was part of

 5  sort of the set-up that we had earlier today, which is when

 6  you're looking at data, you've got to be thoughtful about what

 7  the patterns are that it's showing and know how to analyze it.

 8        So many of you probably would have heard this phrase at

 9  some point in your life, that correlation is not equal to

10  causation.  It's the same thing.  It's related, actually, to

11  the apples-versus-apples comparison.

12        So I'll walk you through a little bit of it, but that's

13  just sort of the starting point for us here.

14  Q.   Okay.

15        And we start, it looks like, where we just were.  We

16  start here talking about Professor Shaked's off-label

17  comparison rate.

18        Is that right?

19  A.   That is correct.  This is actually from his testimony.

20  Q.   Okay.

21        This is a chart from his PowerPoint presentation.

22        Is that right?

23  A.   Yes, ma'am.

24  Q.   Okay.

25        And we recreated it here to make a second slide.  Why
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 1 do we do that?

 2 A.   We recreate it here because if you're looking at the

 3 numbers, you're saying to yourself, all right. 22.3 percent,

 4 I just showed you that. 11.2 percent, I just showed you this.

 5 This is literally from his exhibit, his slide, his

 6 presentation.

 7   22 is twice 11, right? So 11 times 2 is 22. You look

 8 at these bars, they don't look -- the red bar doesn't look

 9 like it's twice as high as the blue bar. All right. It looks

10 like it's, like, four times as high. And you might say, well,

11 why is that? 22 is literally twice as high as 11. Look at

12 the Y axis. The Y axis starts at 8. You shouldn't be

13 starting at 8. You should start it at zero.

14 Q.   So if we go back to Professor Shaked's graph, we realize

15 he's started not at zero but at 8?

16 A.   Correct.

17 Q.   Okay.

18   And what happens when you fix that?

19 A.   If you start it where you should start it, which is zero,

20 you see what makes sense. 11 is basically half of 22. The

21 blue bar is half the height of the red bar.

22 Q.   Okay.

23   And that -- this difference, the actual difference

24 between 11.2 and 22.33, is that the difference that goes away

25 when you fix the error you just showed us?

1   A.   That is correct. So I would say this is not a real

2   difference. This is an erroneous difference because if you

3   fix the error, it goes away.

4   Q.   Okay.

5   So two problems. Number one, the scale of the graph

6   was messed up.

7   Right?

8   A.   Correct.

9   Q.   And number two, when you actually do the math the right

10 way, there's actually no difference.

11 A.   Correct.

12 Q.   Okay.

13   Going back to correlation is not causation. Do you

14 have an example that you can help walk us through to explain

15 what you mean by that?

16 A.   Sure.

17   And -- and as I talk about the example, remember the

18 reason why it is you see two groups of doctors: influenced

19 and non-influenced. The influenced doctors have a higher

20 off-label rate. I think that is an error, but forget about

21 that for a moment. Suppose that it's true. Suppose that it's

22 true that influenced doctors have a higher off-label rate than

23 the non-influenced doctors. Why is it? Is it because of the

24 influence, or is it because of something else? Is it because

25 of any of those 20 other factors? How do you suss that out?

1   That is the problem of correlation versus causation.

2   Q.   Okay.

3   A.   So here I have a slide.   It's not that cleverly titled.

4   It says, "Ice Cream and Shark Attacks."   Okay?

5   Q.   Okay.

6   A.   Let's suppose that you are looking at some data for a

7   project and you saw that shark attacks happened more on days

8   with lots of ice cream consumption.   Shark attack happen more

9   on days with lots of ice cream consumption.   You're thinking,

10   okay, what is this guy talking about?   What would you infer

11   from that?   Would you infer from that that ice cream

12   consumption leads people to get bit by sharks?

13   Q.   Probably not.

14   A.   Probably not.

15   Would you infer from that that shark bites lead people

16   to seek ice cream?   Probably not.

17   Q.   Probably not.

18   A.   Maybe on the back end after surgery and some medications,

19   but probably not.

20   Q.   Right.

21   A.   Might there be some other factor that you're missing?

22   The answer is yes, there might be.

23   So what do people do on hot days?   When the sun is out,

24   it's hot outside, like it was yesterday, people go to the

25   beach.   They go to the beach.   Where I'm from in

1 Massachusetts, there are sharks that are out and about.

2 People will get bit by sharks. They will eat more ice cream.

3   So this is sort of a textbook example -- it's an

4 example I give my students out the gate of causation not being

5 the same thing as a - correlation not being the same thing as

6 causation.

7   And the bottom description says what you need to know.

8 If you want to establish a causal connection, a causal link,

9 you need to account, you need to control for key factors that

10 are affecting the outcome of interest. That's what you've got

11 to do.

12 Q.   Does that mean, Dr. Jena, that we can look at two things,

13 we can think they're related, but there could actually be a

14 third thing that is causing the result?

15 A.   That could be true. In fact, there could be a third,

16 fourth, fifth, sixth and you could go all the way up -- there

17 are many things. There could be many things that are

18 impacting the result.

19 Q.   Okay.

20   Do you have another example to help us understand this

21 issue?

22 A.   I do. So this is a baseball example. I don't know if

23 any of you watch baseball or play baseball. I saw on the news

24 yesterday that the Phillies are playing the Mets in London as

25 opposed to here. So that's --

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 1  Q.   Correct.  Correct.

 2  A.   -- good.

 3       So I don't watch baseball.  I don't play baseball.  But

 4  I will tell you that when I go into a patient's room at MGH,

 5  if they are wearing a Red Sox hat, the first question that I

 6  ask them is -- or say to them, I love football.  And they look

 7  at me, irate, and that serves two purposes.  One is it builds

 8  a connection with the patient, and two is that they're

 9  cognitively with it.  They're going to do all right.  All

10  right.

11  Q.   All right.

12  A.   But here's an example I want to show you.

13  Q.   Yes.  Okay.

14  A.   All right.

15  Q.   So we have group one.  We have ten MLB outfielders; group

16  two, ten MLB catchers.  Total run scores higher in the

17  outfielders than the catchers.

18       Why is this important?

19  A.   Good question.  Well, it's not important in and of

20  itself, but it's important because it illustrates a point.

21  Q.   Okay.

22  A.   Suppose you had the hypothesis that a catcher -- you

23  know, catchers are down there and behind the batter; they're

24  leaning down.  Maybe it happens that catchers would score

25  fewer runs because they're slower.  That's a hypothesis that
```

1   you could make.

2   And then you look at the data, you see what it says.

3   It says, oh, look. Catchers have a total of seven runs scored

4   per season, whereas outfielders, who are always running

5   around, they have 23 runs scored for the season. And the

6   conclusion that you might make, incorrectly so, is that

7   outfielders score more runs because they are faster.

8   Now, is that true?

9   Q.   Okay.

10 A.   How would we figure this out?

11   Well, there's two ways you could figure it out. The

12 first is you literally take catchers and outfielders and you

13 have them run against each other and see who's faster, the

14 equivalent of going to the medical records to figure out the

15 ground truth. You can figure out what happened. You don't

16 have to rely on other types of data to help you answer the

17 question.

18   But suppose you can't do that. You can't do a

19 head-to-head race between the catcher and the outfielder to

20 figure out if one is faster. You just look at the data.

21   And what you see on the data is that outfielders,

22 they're different. They're different in a few ways. So yes,

23 they have more runs scored. But look at the average number of

24 games that they play. The outfielders play 75 games. The

25 catchers play half that. 39 games. The outfielders have 200

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 1 chances at bat. The catchers maybe, maybe not are slower.

 2 They only have 120 chances at bat.

 3   The point is that the outfielders have a lot more

 4 opportunity to score runs. And maybe that is why they're

 5 scoring runs, not because they're slower -- not because the

 6 catchers are slower than the outfielders. The outfielders

 7 just have more opportunities to make runs.

 8 Q. Okay.

 9   So what can we do if we want to make a true comparison

10 here? How could we look at this?

11 A. So if you wanted to make a true, what I might say, or you

12 might say apples-to-apples comparison, you try to make the

13 groups look more similar. Literally apples to apples.

14   So group one you say, all right. We're going to take

15 outfielders who appeared in at least 80 games and had at least

16 100 opportunities at bat. We do the same criteria for group

17 two, the catchers: 80 games and a hundred opportunities at

18 bat. If you make these two groups look more similar, what do

19 you find? The total runs scored are 21 and 20. They're 21

20 and 20. And so what's the conclusion?

21 Q. That's very different from where we started.

22   Right?

23 A. That is very different.

24 Q. Okay.

25 A. Correct.

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1 Q.   All right.

2   And what is the conclusion here?

3 A.   So the conclusion here for this sort of toy example is

4 that outfielders and catchers who have similar playing time,

5 similar numbers of games, similar opportunities at bat, they

6 score nearly the same number of runs.

7   So your hypothesis -- or I'll blame it on me. My

8 hypothesis that catchers score more runs -- sorry -- catchers

9 score fewer runs because they're slower, that hypothesis that

10 I started with was incorrect, because when I made that

11 apples-to-apples comparison, they scored the same number of

12 runs.

13 Q.   How does that -- how does the example that we just went

14 through affect or impact the analysis that you did here in

15 this case?

16 A.   So it impacts it because when you see a group of

17 physicians who are, let's say, quote-unquote influenced and

18 not influenced and you see differences in the rates of

19 prescribing, let's say off-label prescribing, the first

20 question that you have to ask yourself is, is this an

21 apples-to-apples comparison? Are these two groups the same

22 except for the fact that one group was, quote-unquote,

23 influenced and the other group wasn't? Or are these groups

24 different in other substantive ways that might be -- would

25 explain the prescribing differences that you see?

1 Q. Okay. And we're going to get to that right now.

2   Apples to oranges. Okay.

3   Tell us: Doctors contacted by Janssen are different

4 than doctors who are not, what analysis did you do here, and

5 what example is this, Dr. Jena?

6 A. So I'm going to show you an example, and then I'm going

7 to show you something more systematic in a moment. And I want

8 to say the following.

9   I find that examples are very useful because they can

10 tell the story. You don't want to stop there. You do want to

11 be skeptical and say, all right. How did I pick this example?

12 I'm going to show you the more systematic data to surround it,

13 but it is useful to see a story behind a data point.

14   So these are two physicians: one physician who was

15 contacted, Dr. Mills, another physician who was not contacted

16 by Janssen, Dr. Mejia.

17   So Dr. Mills was contacted. Look at his specialty.

18 His specialty is HIV. Look at the non-contacted physician.

19 Specialty is psychiatry and neurology. Look at where these

20 two doctors practice. The contacted doctor works in a

21 practice in a large medical group in Los Angeles. The

22 non-contacted doctor is in a psychiatry in neurology practice,

23 not an HIV or infectious disease practice.

24   The contacted doctor, Dr. Mills, is a principal

25 investigator, meaning they are a researcher in HIV. So they

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1   do HIV research. That's the contacted doctor. Look at the

2   non-contacted doctor. They are not an HIV researcher.

3   And then look at the number of prescriptions. 15,478

4   prescriptions among this contacted doctor. Three among the

5   non-contacted doctor.

6   So you look at this and you say, well, is the reason

7   this doctor has 15,000 prescriptions more than the

8   non-contacted, is it because they were contacted? Is this an

9   apples-to-apples comparison? Clearly not. They are different

10   in so many other dimensions. The contacted doctor -- this is

11   a bread-and-butter HIV doctor. The non-contacted doctor is

12   not.

13   Q.   What happens when you look at this on a graph, Dr. Jena?

14   A.   So when you look at this on a graph in what I would

15   describe as sort of a more systematic way -- using the example

16   as a starting point, when you look at this in a more

17   systematic way, what do you see? Do we see that contacted and

18   non-contacted doctors are similar or different? And what we

19   see is that they are very different in a few different

20   domains.

21   So look at those first two bars. These are infectious

22   disease specialists. For contacted doctors, 49 percent are

23   infectious disease specialists. How about non-contacted

24   doctors? Only 12 percent. Very different. The doctors who

25   are getting contacted by Janssen are way more involved in

1   infectious disease care.

2   Look at prescriptions. That's the second sort of set

3   of bars. "Prescribe HIV medications to at least five Medicare

4   patients." This is trying to capture whether or not this

5   doctor sees a lot of HIV patients or not.

6   94 percent of contacted doctors fall into that

7   category, seeing a lot of HIV patients. A third of that, 37

8   percent, fall into that category for non-contacted. The

9   contacted doctors see a lot more HIV patients.

10   And the last thing is look at Prezista and Intelence.

11   The contacted doctors prescribe way more Prezista and

12   Intelence. Is it because they're contacted, or is it because

13   they're infectious disease specialists; that they actually see

14   a lot of HIV patients?

15   What this graph shows you is that when you compare

16   contacted to non-contacted doctors in a simple comparison, you

17   are making an apples-to-oranges comparison.

18   Q.   What happens, Dr. Jena, if you try to make an

19   apples-to-apples comparison?

20   A.   So when you make an apples-to-apples comparison, it's

21   like outfielders and the catchers. You don't just look at

22   them generally, because they differ in a lot of ways. You try

23   to pick outfielders and catchers who are more similar, who've

24   got the same amount of time in the game, same amount of times

25   at bat. Apples to apples. When you do that, you find that

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 1  there is no difference between contacted and non-contacted

 2  doctors in terms of their off-label rates.

 3          So let me show you what this means in this graph here.

 4  So the first panel, if you will, on the left, that's what

 5  Professor Shaked has shown -- shown you.  We've talked about

 6  it a few times.  He says that contacted physicians have an

 7  off-label rate of 22 percent, non-contacted, 11 percent.  All

 8  right.

 9          Now just look at physicians with one initiation.  You

10  just hold that one factor constant.  You try to make an

11  apples-to-apples comparison.

12  Q.   Dr. Jena, let me just stop you right there.

13          Is this what -- when we go back to the baseball example

14  you gave us, is this where we're trying to make sure that the

15  outfielders and the catchers played in the same amount of

16  games, had the same number of at bats?  Is that what we're

17  trying to do here?

18  A.   I couldn't say it better myself.  That's exactly what

19  we're doing here.

20  Q.   Okay, okay.

21          Sorry, go ahead.  So walk us through the graph then.

22  A.   So we're trying to make sure that the contacted and

23  non-contacted doctors, just like the outfielders and the

24  catchers, are just more similar.

25          So look at the second or the third set of bars.
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1   Physicians with two to ten initiations. These are doctors who

2   have initiated patients on therapy between two and ten times.

3   Trying to pick a group of doctors who are similar in that

4   respect. And what do you see with respect to off-label

5   prescribing rates? The non-contacted doctors actually have

6   slightly higher off-label rates. But you certainly don't see

7   that the blue bar is higher than the red bar there in any of

8   these different analyses.

9   So when you compare doctors who are more similar, you

10   no longer see a difference between contacted and

11   non-contacted. Why? It's because being contacted is just a

12   proxy for something else. It's a proxy for being an HIV

13   doctor. It's a proxy for seeing lots of HIV patients. It's a

14   proxy for prescribing more HIV drugs.

15   Q.   Okay.

16   And do you have an example from the data that has an

17   apples-to-apples comparison?

18   A.   I do. And, again, this is just one example. You saw the

19   systematic data earlier.

20   These are two doctors, both who are listed here. One

21   contacted, one non-contacted. Dr. Dobbs was contacted;

22   Dr. Weaver, not contacted. Look at their specialties. Both

23   are involved in HIV care. Look at where they practice. They

24   both practice in larger medical centers. They are both HIV

25   researchers. In terms of the number of prescriptions for HIV

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 1   drugs, antiretrovirals or ARVs, 4,000, 6,000, 5,000, 6,000, in

 2   that range.  High prescribers.

 3        Now, here's the take-home.  Look at that very last row.

 4   Off-label rate calculated by Professor Shaked for these two

 5   doctors, 52 percent and 55 percent.

 6        This is just a simple example to show that when you

 7   compare apples to apples, like to like, you don't find that

 8   there's any difference in off-label promotion -- or any

 9   difference in off-label prescribing rates between the two

10   types of doctors.

11   Q.   If Janssen's marketing efforts were truly causing

12   physicians to prescribe Prezista and Intelence, what would

13   happen when you compared apples to apples, the same types of

14   doctors?  What would you expect to see?

15   A.   If you did that comparison, you would still see a

16   difference in off-label rates.  If we're comparing apples to

17   apples across all domains and we see that contacted doctors

18   have higher off-label rates, then we think maybe that is due

19   to the contact.  That's not what we see.

20   Q.   All right.

21        THE COURT:  Ms. Brown, are you switching to a different

22   topic?

23        MS. BROWN:  I am.  I am, Your Honor.  And I'm very

24   close --

25        THE COURT:  Do you think it's a good time to --
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 1            MS. BROWN:  -- finishing, but I will --

 2            THE COURT:  -- put a placeholder?

 3            MS. BROWN:  Yeah, I will not finish.  Yeah.

 4            THE COURT:  No, no.  If you're going to tell me we're

 5   going to complete the examination, I don't want to stop you.

 6   But we're going to go into Monday, then --

 7            MS. BROWN:  We're are going to go into Monday.  I'm

 8   very close, but not five minutes close.  So we can stop, yes.

 9            THE COURT:  All right.  Well, then, let's do this.

10   Folks, we're going to adjourn for the day.  I want to at least

11   excuse the jurors.

12        Members of the jury, just two quick reminders.  Well,

13   one, have a wonderful weekend.  I'll see you all Monday at

14   9:00.  Two, just remember, that time is coming sooner than you

15   think.  You're going to be able to discuss this case.  But

16   until then, continue to do what you are doing, which is do not

17   discuss the case with each other, but everything else,

18   personal or otherwise, you're free to communicate.

19        And then other than that, I'll see you at 9:00 a.m.

20   Monday.  Thanks for your attention.  I appreciate it.

21         (The jury is excused.)

22            THE COURT:  Dr. Jena, you're excused from the witness

23   box.  Just make sure to return Monday at 9 a.m.

24            THE WITNESS:  I'll be here.

25            THE COURT:  All right.  Thank you.
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1   THE WITNESS: Thank you.

2   THE COURT: So there's at least one issue that we

3   need to address today on the record. I believe that came up

4   on sidebar, Mr. Wirmani, with the -- and Ms. Brown -- with the

5   additional documents that are related to the HCC investigation

6   that Ms. Brown has requested to move in, which, in part, is

7   the catalyst to the adverse inference instruction. Right?

8   The adverse inference instruction doesn't say, Withheld the

9   investigation report and a letter from Joanne Cesario. It

10 says, Documents.

11   And so I don't know who's handling this from Relators.

12 Mr. Wirmani, is this still your issue or Mr. Marketos'? Who

13 is handling it?

14   Are you still objecting to the admissibility of those

15 additional documents?

16   MR. WIRMANI: We are, Your Honor.

17   THE COURT: And what's the basis for that?

18   And by the way, maybe you've addressed my concern then.

19 Right? So I've given a negative or adverse inference

20 instruction. You're not required to present all these

21 documents in your examination of Ms. Kaucher, but you put

22 before the jury a couple of things.

23   First of all, identify the Frank Murphy issue. Right?

24 And I -- again, I'm not alleging that you attempted to

25 misrepresent that Frank Murphy was never interviewed, although

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 1   we know he was.  Right?  Because there's a document that

 2   identifies Dr. Patel's interview of Frank Murphy.  But you've

 3   put before the jury, on cross-examination, at least in the

 4   investigation report, that with respect to one allegation, it

 5   states there that Mr. Murphy was spoken with.  And with

 6   respect to another allegation, it doesn't say he was spoken

 7   with there.  And there's a clear implication there that he was

 8   not interviewed, although there's a document to confirm that

 9   he was.

10        Why wouldn't that be permitted to be before the jury,

11   especially when the attempt of these documents is to make sure

12   that they get at least a full picture, right?  And it's not

13   like I gave Ms. Brown the opportunity to examine Ms. Kaucher.

14   In fact, I denied that request, allowing you to have the last

15   word on documents with that particular witness, even though

16   Ms. Brown, as the trial attorney, didn't have access to those

17   documents in her direct exam.

18        So tell me why these shouldn't be in there, at least

19   with Frank Murphy's interview.

20        MR. WIRMANI:  Your Honor, I would say the overall

21   investigation report that lists everyone at the top that was

22   interviewed included Frank Murphy.  So it's clearly in the

23   report.  The fact that there's no -- I mean, the question was

24   specific to allegation 2.  There's no specific reference in

25   the investigation report to the fact that this occurred.
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 1              THE COURT:  And allegation 2 deals with the off-label

 2   marketing, right?

 3              MR. WIRMANI:  It is --

 4              MS. BROWN:  Yes, Your Honor.

 5              THE COURT:  But doesn't the interview note say,

 6   basically, that he was questioned about off-label marketing?

 7              MS. BROWN:  Yes, Your Honor.

 8              MR. WIRMANI:  And, Your Honor, I think the -- what

 9   number 2 shows, at the top there's the health care

10   investigation, Grimes and ERRG interview the following

11   individuals in furtherance of the investigation.  It goes down

12   the list.

13         The only thing that was said was the significance to

14   the fact that for whatever reason, they didn't find it

15   significant enough to put into the report.  That's what was

16   pointed out to the jury.  I mean, if the Court really thinks

17   it's that big an issue, then it can be -- the rest of it can

18   be redacted and Frank Murphy's denial --

19              THE COURT:  Well, I'll get to the next issue.  I

20   actually don't think that's the bigger issue.  I just wanted

21   to see if you would at least concede that that part should

22   come in.

23         But let me give you the bigger issue, which is where I

24   have it.  Right?  So the negative inference instruction

25   basically informs the jury that Janssen withheld these
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 1   documents related to the investigation. We don't identify all

 2   the specific documents in that instruction. Right?

 3   Would you agree with me there?

 4   MR. MARKETOS: Yes. That's correct.

 5   THE COURT: All right. So we just say documents

 6   plural.

 7   And I also -- and the main gist of that instruction or

 8   the crux of it is me telling them they may -- or they're

 9   permitted but not required to infer that Janssen knew that

10   these documents would be harmful to Janssen when they withheld

11   them. Right? That is the -- that is the painful sanctioning

12   part of that instruction to Janssen.

13   Would you agree with me there?

14   MR. WIRMANI: Sure.

15   THE COURT: So in that, you would also agree with me

16   that I'm not instructing the jury that they're required to

17   make that negative inference; I'm only telling them that they

18   may make it. Right?

19   MR. WIRMANI: Yes.

20   THE COURT: I presume, and you can correct me if I'm

21   wrong, that Relators in closing, in some part of your closing

22   argument, is going to bang that drum and say they should make

23   that negative inference.

24   Am I mistaken about that?

25   MR. WIRMANI: No, we will.

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 1            THE COURT:  And so then now comes to where I'm
 2   concerned.  Janssen has the equal right in closing.  And I
 3   have to -- I have to presume they're going to at least touch
 4   on this issue in closing; that the jury should not make a
 5   negative inference here or not draw that inference because the
 6   documents that were withheld -- and that cannot be disputed.
 7   So I think Janssen's well aware they can't dispute what I've
 8   actually told them is factual.
 9        But the part about whether they should infer these
10   documents were harmful to Janssen, they knew it, that part,
11   they can't be handcuffed in arguing.  And so if you've
12   cherry-picked only two documents, the investigation report and
13   the letter from Cesario, my concern is that I've handcuffed
14   Ms. Brown in her closing to say, Well, wait a minute.
15   Your Honor, we withheld these documents.  That is a collection
16   of more than just those two documents.  And when you review
17   those documents in totality, we should have the ability to at
18   least argue before the jury - they don't have to agree with us
19   and Relators don't have to agree with us -- that if they were
20   to review those documents in totality, that it doesn't -- we
21   can make the argument that we did not know it was harmful
22   because, in fact, these are not harmful to us.  We want to
23   argue that they are harmful to the Relators.
24        Why should they be precluded from having access to
25   those additional documents which talk about physician
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1   interviews and otherwise? Because right now, we've -- that is

2   hidden from the jury. Right?

3   MR. WIRMANI: I don't believe that's totally hidden

4   from the jury. The jury is fully aware of what documents are

5   out there because it was discussed. And this wasn't

6   cherry-picked. This was the allegations that Cesario made in

7   detail, and then the culmination of the investigation report

8   was -- described all their investigative steps. It says these

9   people were interviewed.

10   At a point that the reason Janssen doesn't have the

11   additional documents in evidence is because they withheld

12   them. Right? And I don't think it is appropriate for the

13   Court to be going back and trying to cure potential

14   prejudice --

15   THE COURT: Well, I'm not doing that. I'm not curing

16   any prejudice. I mean, the instruction has been given. In

17   fact, it's going to be given twice, which was something that

18   Janssen strongly objected to. And not only will it be given

19   twice verbally to this jury, it will be sitting in writing

20   with the final instructions in the deliberations room. So I

21   don't think I'm sugarcoating this negative inference

22   instruction.

23   But let me ask you this. You provided a report.

24   Right?

25   MR. WIRMANI: Correct.

1   THE COURT: These are underlying documents in support

2 of that investigative report.

3   MS. BROWN: Yes, Your Honor.

4   MR. WIRMANI: Yes.

5   THE COURT: Well, Ms. Brown, you wait.

6   MS. BROWN: Sorry.

7   THE COURT: Let me just hear from Mr. Wirmani.

8   So here we've given them the report, but we won't show

9 them the underlying documents that support the report. And,

10 again, the negative inference instruction doesn't say, Janssen

11 withheld an investigation report and a letter from

12 Ms. Cesario, where now they know what it is, and Janssen

13 fairly can say, Okay. This is all we failed to disclose, and

14 we're going to make the argument here.

15   I will tell you, you haven't convinced me yet. And

16 I'll let Ms. Brown have an opportunity for Janssen to make a

17 record. But, again, you haven't convinced me to preclude

18 these documents.

19   So is there anything more you want to place on the

20 record, Mr. Wirmani?

21   MR. WIRMANI: The negative inference comes from the

22 fact that the investigation report had two sustained

23 allegations when the witness last week testified --

24   THE COURT: Well, then you can make that argument,

25 that this should be -- this shouldn't affect your argument at

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 1   closing, then, that the fact that some folks were interviewed

 2   and these are related to -- not only related to the

 3   investigative report that you submitted in evidence, but they

 4   are the underlying documents in support of that investigation.

 5        When Janssen represented that, Here's the investigation

 6   report, and these are the related documents to the report,

 7   nobody is disputing that they just handed us interview notes

 8   from a separate investigation and a report to a third

 9   investigation and they're combining the two.  It's clear and

10   the -- I presume the Relators have accepted that these

11   documents are all related to the same HCC investigation.

12        So, again, it's not complete.

13        MR. MARKETOS:  I don't think that that's the

14   standard, though.  It's documents were withheld.  It was our

15   redirect.  We put before the jury the documents that we

16   thought were relevant.  There was nothing -- I could

17   understand the Court's concern if there was some contradictory

18   information in the underlying documents or something of that

19   nature, but it is pulled up into the final investigation --

20        THE COURT:  Well, no.  First of all, there is a -- I

21   argue, a contradiction.  Right?  The implication you made that

22   Frank Murphy was only interviewed for one allegation and

23   another, to me, on the face of the interview documents, that

24   appears to be in contradiction.

25        MR. WIRMANI:  I mean, I thought I basically conceded
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 1  that at the bench.

 2          THE COURT:  No, no.  But I just want to make clear.

 3  So that part now you've conceded.  So at the bare minimum,

 4  Frank Murphy's interview goes in.

 5          So then let's take it from there.

 6          One interview note would be admissible.  How is that

 7  complete?  Right?  We have an investigation report, and now

 8  the jury is going to have the appearance that they withheld

 9  documents.  Right?  Because that's all we've described them

10  as, is an investigation report, Joanne Cesario's letter

11  identifying in detail our six allegations, which match the

12  allegations of the report, and then one interview of Frank

13  Murphy.

14          That does not seem fair that one would go in and then

15  we would somehow not put before the jury that there were

16  several interviews.

17          MR. WIRMANI:  I think the jury is fully aware from

18  the questioning that there were other documents that were

19  turned over.  I don't think that was hidden from --

20          THE COURT:  But they don't know what the documents

21  are.

22          MR. WIRMANI:  Well, we said there were interview

23  reports that her name was not mentioned on.  I mean, that's

24  basically the totality of the additional documents, I believe.

25  Unless there's something else in there.
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 1              THE COURT:  But in arguing whether the jury should

 2   draw a negative or adverse inference against Janssen, meaning

 3   these documents that were withheld are harmful, how do you

 4   make an argument -- how does Janssen make an argument that

 5   they're not harmful?

 6              MR. WIRMANI:  Because there's four -- there's four

 7   allegations that are unsubstantiated.  They have -- I put into

 8   the record what the punishment was.  The PIP letter that went

 9   to Frank Murphy.  They can show that discipline was taken.

10         I think the documents in the record give the jury the

11   entire picture of what happened, and this is just cumulative,

12   and Janssen is in that position because they withheld the

13   documents.

14              THE COURT:  Well, Janssen is in the position -- they

15   got a negative -- an adverse inference instruction.  That is

16   not a common instruction to give in a trial.  And I don't even

17   know if you folks have ever been in a trial where that type of

18   instruction has been given.

19         So that is a rarity.  I mean, that is an extreme remedy

20   that I provided because I made findings that this was an

21   extreme discovery violation.

22         But I've heard your point.  I'm telling you that I'm

23   going to allow these four additional documents -- or I'm

24   sorry.  Let me just make sure that I have it right.

25         These additional documents requested by Janssen, I'm
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 1  going to allow it to be admitted.  But, Mr. Wirmani, I will

 2  allow the Relators to move them into evidence.  So you all

 3  tell me how you want to proceed on Monday with those

 4  documents, because what I'm not going to do, based on my

 5  ruling which is coming after Ms. Kaucher, is somehow allow

 6  Janssen to move these documents in where I've now given the

 7  appearance to the jury that somehow the Relators were trying

 8  to somehow keep this at bay.

 9       But I'm going to -- I'm deeming these documents

10  admissible for the reasons why I articulated.  They're all

11  related and the catalyst to the negative or adverse

12  instruction that I've given to the jury.  How do you want to

13  proceed on Monday with these documents?

14       MR. MARKETOS:  Give us a chance to review what

15  Janssen has actually submitted, Your Honor.  We can go back

16  and look if there's anything else that we believe is

17  appropriate and we'll discuss.  But, I mean, if the option is

18  they're coming in, then we're likely to move them into

19  evidence.

20       THE COURT:  All right.  And if there's some

21  additional document that now that I'm -- because I'm

22  inclined to -- well, I'm not inclined to.  I am admitting

23  these documents one way or the other.  If there's additional

24  documents that you received late, you know, as part of this

25  collection, where you're like, Your Honor, we addressed these
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 1 | two documents, but in light of your ruling that these four are

 2 | coming in, we also believe this additional document will be

 3 | coming in, I'm inclined to agree with that reasoning.

 4 |        But I've got the request from Janssen, I've made my

 5 | ruling, and you're going to have to make that determination by

 6 | Monday.

 7 |        Fair enough?

 8 |           MR. WIRMANI:  Okay.

 9 |           THE COURT:  All right.  So that's where we are on

10 | that.

11 |           MS. BROWN:  Thank you, Your Honor.

12 |           THE COURT:  Ms. Brown, do you need to place anything

13 | on the record on that?

14 |           MS. BROWN:  No.  No.  Well argued.  Thank you, Judge.

15 |           THE COURT:  All right.  Do have anything substantive

16 | to discuss?  There is a motion to strike that I'm not going to

17 | deal with today.  I'm going to deal with that motion Monday,

18 | so we can just table it because I think we've had a long day.

19 | But I'm referring to the motion on Dew and Shaked.

20 |        Is that all right with you, Mr. Marketos?

21 |           MR. MARKETOS:  Yes.  Yes, Your Honor.  After

22 | Dr. Jena's finished.

23 |           THE COURT:  And after -- you're right.  After the

24 | completion of Dr. Jena's testimony.  You're right.

25 |        So maybe we can address that Monday with the closing of
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 1  the day like we're speaking now.

 2          MR. MARKETOS:  Yes, Your Honor.  And would Your Honor

 3  prefer a written response from us?  I mean, we could do that.

 4          THE COURT:  It's not my preference.  I'll say what I

 5  said again, Mr. Marketos.  They submitted the motion in

 6  writing.  You're not precluded, and you're going to get an

 7  opportunity to respond in writing.  If you think that that's

 8  an exercise that is a waste of time because you're in the

 9  middle of trial and you want to respond and oppose verbally,

10  you have that opportunity.  So I leave that -- that's your

11  call, not mine.  I am not directing you to put something in

12  writing, but I'm surely not going to prevent you either.

13      So do you want to respond in writing?  Because if so, I

14  want to know today so I'm anticipating something is coming.

15  And if not, Monday at 5 o'clock, you can oppose that written

16  motion verbally, orally.

17          MR. MARKETOS:  I'll put some thought to it,

18  Your Honor.  Well, actually, you wanted to know now.  I think

19  on something like this we'll probably --

20          THE COURT:  How's this?  If you don't know -- give it

21  thought over the weekend, but Monday morning, you're going to

22  need to tell me.

23          MR. MARKETOS:  Yes, Your Honor.

24          THE COURT:  Fair enough?

25          MR. MARKETOS:  Yes, Your Honor.  Thank you.
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1   THE COURT: All right. So that's -- is that the

2 substantive issue that's tabled? Because if so and if we just

3 have logistical things, I would like to go off the record.

4   But before I do that, anything substantive we have to

5 discuss right now?

6   MR. MARKETOS: Not from us, Your Honor.

7   THE COURT: Ms. Brown?

8   MS. BROWN: No.

9   THE DEPUTY COURT CLERK: All rise.

10   (Court concludes at 5:12 p.m.)

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United States District Court
District of New Jersey

1   FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

2   -

3

4   I certify that the foregoing is a correct transcript from

5   the record of proceedings in the above-entitled matter.

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11   /S/ Megan McKay-Soule, RDR, CRR   June 7, 2024

12   Court Reporter   Date

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United States District Court
District of New Jersey

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